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Pharma Rise

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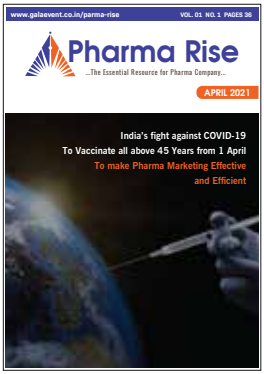
APRIL 2021

India's fight against COVID-19

To Vaccinate all above 45 Years from 1 April

To make Pharma Marketing Effective and Efficient



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INDEX

Covid vaccine age limit eased, MHA issues new guidelines to curb spread: Top developments

In a big boost to India's inoculation drive amid a surge in new Covid-19 cases, the Central Government has eased the age limit on vaccination, allowing all those above 45 years in age to get the dose from 1 April.

The nationwide vaccination drive was rolled out on 16 January with healthcare workers getting inoculated while frontline workers began getting the shots from 2 February.

The second phase of the world's largest vaccination campaign commenced on 1 March for those who are over 60 years of age and for people aged 45 and above with specified co-morbid conditions.

The government's move to ease the age limit for coronavirus vaccination is expected to provide a big boost to the inoculation programme in the country amid a recent spurt in daily Covid-19 cases in some states.

In another major development, the Ministry of Home Affairs (MHA) has issued new guidelines, asking all states to enhance the proportion of RT-PCR tests, strictly enforce the 'test-track-treat' protocol and speed up the pace of vaccination to cover all priority groups.

All you need to know about India's fight against Covid-19

India to vaccinate all above 45 from 1 April

Union minister Prakash Javadekar has said that now even people without comorbidities who are more than 45 years of age can get vaccinated.

"Today after discussion and on the advice of the task force and scientists, it was decided that from April 1 the vaccine will open for everybody above 45 years of age," he said.

"Our appeal is that all above 45 years should take vaccine as early as possible, that will provide them the shield against coronavirus and they should register for getting vaccinated."

Javadekar said the Cabinet also decided that the second dose of the vaccine can be taken between four and eight weeks, on the advice of doctors. It was allowed to be taken between four to six weeks earlier, but scientists have now said that taking the second dose between four and eight weeks gives improved results.

He said till this day, 4.85 crore doses of the vaccine against Covid-19 have been

administered with more than 32 lakh people getting the jabs in the last 24 hours, which was the highest single-day vaccination so far.

Vaccines are available in enough number and there is no scarcity and the supply chains and supply line is intact, he said.

To a question on rise in Covid cases in some states, he said the central government is in touch with them and there will be effective management.

"We hope that virus would not be allowed to spread."

Govt tells states to 'test, track, treat' to counter Covid surge

The government has issued a fresh set of guidelines directing all states and Union Territories (UT) to 'test-track-treat' in a bid to counter the renewed surge of coronavirus infections.

MHA has asked all states and UTs to enhance the proportion of RT-PCR tests, strictly enforce the 'test-track-treat' protocol and speed up the pace of vaccination to cover all priority groups.

The new set of guidelines issued by the MHA will be effective from 1 to 30 April.

The MHA noted in its guidelines that while the Covid vaccination drive is proceeding smoothly, the pace is uneven across different states and UTs and, the slow pace of vaccination in some states and UTs is a "matter of concern".

The guidelines said the vaccination in the present scenario is critical to break the chain of transmission and hence all state and UT governments should rapidly step up the pace to cover all priority groups in an expeditious manner.

Delhi, Karnataka see record daily spike in cases

Delhi and Karnataka have registered a record spike in fresh Covid-19 cases. While Delhi saw an increase of 1101 new cases, its highest since December 19 last year, Karanataka added more than 2,000 cases in the last 24 hours.

Amid the surge and the state government's measures to contain the spread, the Karnataka government had decided to make a negative Covid report not older than 72 hours mandatory for travellers from Punjab and Chandigarh. The government had already made the provision for those from Kerala and Maharashtra.

The rising number of coronavirus cases in Delhi prompted authorities to impose restrictions on Holi celebrations. Citing the prevailing Covid-19 situation, the AAP-led Delhi government has imposed a ban on Holi celebrations in public places.

Maharashtra's Covid numbers

- *Maharashtra has reported 28,699 new Covid-19 cases, 13,165 recoveries, and 132 deaths in the last 24 hours.*
- *According to the State Health Department, the total count of cases has gone up to 25,33,026 including 2,30,641 active cases and 22,47,495 recoveries.*

- *Pune district reported 5,722 positive cases and 38 deaths in the last 24 hours.*
- *The cumulative cases in the district stand at 4,79,521, while the total number of recoveries stand at 4,27,400.*
- *There are 42,650 active cases in Pune. As many as 9,640 people in the district succumbed to the virus.*
- *Mumbai reported 3,512 new Covid-19 cases taking the cumulative cases in the capital city to 3,69,426.*
- *While 1,203 people have recovered from the disease, eight people succumbed to the virus in the last 24 hours.*
- *Total recovered cases in the city stand at 3,29,234 and the death toll is 11,600, Mumbai has 27,672 active cases.*

India's total cases of mutant Covid-19 variants reach 795

The total number of cases with the UK, South Africa and Brazil variants of SARS-CoV-2 in the country has reached 795. From 400 cases reported on March 18, the infections by mutant strains have increased to 795 in the country.

Minister of State for Health Ashwini Choubey told Rajya Sabha on March 16 that no case of reinfection by mutant variants of SARS-CoV-2 virus has been reported from India so far.

According to the World Health Organisation (WHO), in the three countries where the pandemic is being driven by the variant mutants of SARS-CoV-2 virus, namely the UK, South Africa and Brazil, the South African and Brazilian variants have the potential to reinfect persons who have been previously infected with SARS-CoV-2, he said in a written reply.

The UK variant of SARS-CoV-2 was first reported in India on December 29.

International flights remain suspended in India till April-end

In view of the novel coronavirus pandemic, the Indian government on Tuesday extended the suspension on scheduled international passenger flights till 30 April, 2021.

"However, international scheduled flights may be allowed on selected routes by the competent authority on a case-to-case basis," noted the Directorate General of Civil Aviation (DGCA) in a circular.

The circular said the suspension does not affect the operation of international all-cargo operations and flights specifically approved by the DGCA.

Scheduled international passenger services continue to remain suspended in India since March 23 due to the coronavirus pandemic.

Strides gets USFDA approval for Potassium Chloride for Oral Solution

Potassium Chloride Oral Solution is indicated for the treatment and prophylaxis of hypokalemia

Strides Pharma Science announced that its step-down wholly-owned subsidiary, Strides Pharma Global Pte, Singapore, has received approval for Potassium Chloride for Oral Solution USP, 20 mEq from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Potassium Chloride for Oral Solution USP, 20 mEq, of Pharma Research Software Solution.

According to IQVIA MAT January 2021 data, the US market for Potassium Chloride for Oral Solution USP, 20 mEq is approximately $56 million. The product will be manufactured at the company's facility at Bangalore and will be marketed by Strides Pharma in the US market.

The company has 127 cumulative ANDA filings with USFDA of which 100 ANDAs have been approved and 27 are pending approval.

Potassium Chloride Oral Solution is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.

AstraZeneca Pharma India gets DCGI approval for Osimertinib tablets

It is now approved as monotherapy for adjuvant treatment after complete tumour resection in patients with NSCLC

AstraZeneca Pharma India has received Import and Market Permission in Form CT-20 (Subsequent New Drug Approval) from the Drugs Controller General of India for Osimertinib 40mg/80mg film-coated tablets (Tagrisso).

Osimertinib 40mg/80mg film- coated tablets as monotherapy is now approved for additional indication for the adjuvant treatment after complete tumour resection in patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon19 deletions or exon 21 (L858R) substitution mutations.

The receipt of this permission paves way for the launch of Osimertinib 40mg/80 mg film-coated tablets into a new disease area in India, subject to the receipt of related statutory approvals and licenses.

Drugs Controller General of India

WuXi Biologics to acquire CMAB Biopharma Group

Form strategic partnership with CBC Group

WuXi Biologics announced it has entered into a purchase agreement with CBC Group (CBC), a healthcare-dedicated investment firm, and other companies including Ming Bioventures under which WuXi Bio will acquire over 90 per cent interest of CMAB Biopharma Group (CMAB). The transaction is expected to close in the second quarter of 2021.

As a Contract Development and Manufacturing Organization (CDMO) based in Suzhou, China, CMAB provides comprehensive services from cell-line development, process development to clinical GMP manufacturing and has over 250 employees. Upon transaction completion, WuXi Biologics will increase 7000L drug substance capacity (MFG21) and drug product capacity (DP11) for liquid and lyophilization within its global manufacturing network.

Furthermore, WuXi Biologics and CBC will also establish a strategic collaboration to enable CBC portfolio companies to discover, develop and manufacture biologics.

NPPA extends ceiling prices of Heparin Injection till Sept 2021

The decision is taken based on the movement in API prices

The National Pharmaceutical Pricing Authority (NPPA) has extended the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml upto September 2021.

Earlier, vide SO. 2151(E) dated June 30, 2020, the authority had revised the ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml which was applicable up to December 31, 2020, and the same was extended up to March 31, 2021.

However, in the 84th meeting under the DPCO, 2013, on March 10, 2021, the NPPA authority deliberated upon the matter in detail and considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19 and opined that any situation of non-availability due to increase in the price of APIs needs to be seen from a public interest perspective.

During the meeting, based on the report of the API Monitoring Committee highlighting the constant price increase of APIs and gauging the drug requirement in the market, NPPA has decided to further extend the ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml should be further extended up to September 2021, or until further order, whichever is earlier, in public interest.

The committee stated, "NPPA may continue with the increased ceiling price for Heparin Injection 1000IU/ml and 5000IU/ml, to ensure continuous availability of this essential drug. The ceiling price of Heparin may be reviewed after the COVID-19 situation becomes normal or earlier as deemed fit."

Besides this, the authority has also directed that the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of Heparin 1000IU/ml Injection and Heparin 5000IU/ml Injection up to September 30, 2021, or until further order, whichever is earlier.

The meeting took place under the Chairmanship of Chairman, NPPA and attended by key members of NPPA along with Dr Vinod Kotwal, Member Secretary, NPPA, A K Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department

of Expenditure, A Srija, Economic Advisor, Department of Economic Affairs and Dr V G Somani, DCG(I), CDSCO, Ministry of Health & Family Welfare.

Dr Ketan R Patel, Chairman and MD, Troikaa Pharmaceuticals said, "Due to continuous demand of Heparin Injection for use in COVID- 19 patients having serious infection, the prices of the API continue to be high. In view of this, the decision of the government of India is appreciable and in line with the prevailing market situation."

Bill seeking to endow national i mportance tag to six pharma institutes tabled in Lok Sabha

The National Institute of Pharmaceutical Education and Research (Amendment) Bill, 2021 makes provisions to grant the status of national importance to six institutes based in Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli.

DV Sadananda Gowda, Union Chemicals and Fertilisers Minister introduced a bill in Lok Sabha that seeks to provide the national importance tag to six pharma education and research institutes in the country.

The National Institute of Pharmaceutical Education and Research (Amendment) Bill, 2021 makes provisions to grant the status of national importance to six institutes based in Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli.

The National Institute of Pharmaceutical Education and Research Act, 1998 (13 of 1998) was enacted to declare the National Institute of Pharmaceutical Education and Research at

Mohali, Punjab to be an institute of national importance and to provide for its incorporation and matters connected therewith.

The Act was subsequently amended in 2007 to empower the central government to establish similar institutes in different parts of the country. Thereafter, six new institutes in Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli were established during 2007-08.

"A need is felt to bring clarity that the six institutes so established, as well as any other similar institute to be established under the said Act, shall be institutes of national importance," the statement of objects and reasons regarding the bill said.

In order to coordinate the activities of all such institutes, to ensure coordinated development of pharma education and research and maintenance of standards, etc., there is a need to establish a central body, to be called the Council, it noted.

Also, there is a need to rationalise the Board of Governors of each such institute and to widen the scope and number of courses run by such institutes, it said.

Also, there is a need to rationalise the Board of Governors of each such institute and to widen the scope and number of courses run by such institutes, it said.

CRISPR-based cancer therapies likely to be a disruptive technology in healthcare: GlobalData

Three leading companies racing to bring CRISPR therapies to the clinic are CRISPR Therapeutics, Intellia Therapeutics and Editas Medicine

Clustered regularly interspaced short palindromic repeat (CRISPR) therapies are one of the most potentially powerful and transformative technologies in human history, according to GlobalData. Expected to be able to prolong the life of cancer patients by decades, compared to the current performance of blockbuster drugs that prolong life by a few years at best, CRISPR-based therapies will inevitably transform the lives of patients and the shape of the industry if they are brought to market.

Three leading companies are racing to bring CRISPR therapies to the clinic, including CRISPR Therapeutics, Intellia Therapeutics and Editas Medicine.

Adam Pearson, Senior Oncology Analyst at GlobalData, compares the three companies, "CRISPR Therapeutics has the largest market cap of the three, at $10.1 billion, with a clinical development program that is more advanced than those of Intellia and Editas. CRISPR Therapeutics has already published promising data on the use of CRISPR in β-thalassemia and sickle cell disease in the New England Journal of Medicine. The company has also initiated early-stage clinical trials for its immuno-oncology program, which is based on the development of allogeneic chimeric antigen receptor T(CAR-T) cells targeting well-characterised targets in haematological malignancies such as CD19+ and B cell maturation agent. The development of allogeneic CAR-T cells may circumvent issues with manufacturing and the costs associated with autologous CAR-T cells, which have already demonstrated impressive durable responses in patients with haematological malignancies."

Intellia's NTLA-2001 uses an in vivo approach to tackle a rare hereditary disorder, transthyretin amyloidosis, for which only chronic treatment options are currently available.

Pearson comments, "Similar to CRISPR Therapeutics, Intellia is also considering sickle cell disease as a target indication, but the

company is slightly behind CRISPR in terms of clinical development, potentially indicating a future second to market disadvantage.

"Intellia has established high-profile collaborations with Regeneron and Novartis, which will boost its ability to navigate a successful route to market and provide the company with necessary infrastructure and experience in drug development and commercialisation."

Editas Medicine has the smallest market cap of the three companies working in this area, and currently only has a single agent in clinical development: EDIT-101.

Pearson adds, "Unlike the other companies, Editas is focusing on ocular diseases, specifically Leber Congenital Amaurosis, indicating the potential to monopolise this space."

Each company has overlapping and distinct target indications, and all three are targeting haematological disorders and developing an immuno-oncology program, either in the clinical or pre-clinical stages.

Pearson concludes, "This suggests potential future competition, but also indicates that each company has room to carve out and monopolise distinct markets. CRISPR Therapeutics has a head start in terms of its clinical development and raising capital, and represents a safer choice for investors as a result. However, each of these companies produce little to no current revenue, and current expectations are contingent on favourable results from upcoming clinical trials, which are still in the early stages of development.

"Future challenges in this space include how to develop a fair pricing strategy, the logistics of offering broad access to the most needy populations in underserved markets (such as sickle cell patients in Africa), and potential unfamiliar adverse events associated with this novel modality of therapy. However, the potential upside for patients and long-term investors is huge."

Key Statistics for Leading CRISPR-Based Therapeutic Companies and Agents in Clinical Development

Company	Market Cap ($)	Collaborators	Portfolio	Target Indication(s)	Stage of Clinical Development
CRISPR Therapeutics	10.1bn	Vertex	CTX001	**Hemoglobinopathies** (β-thalassemia and sickle cell disease	Phase I or I/II
			CTX110 CTX120 CTX130	**Immuno-Oncology** (allogeneic CAR-T development for hematological and solid tumors)	Phase I
Intellia Therapeutics	4.02bn	Regeneron	NTLA-2001	**In Vivo** (Transthyretin amyloidosis)	Phase I
		Novartis	CRISPR/Cas9	**Ex Vivo** (Sickle cell disease)	Phase I/II
Editas Medicine	3.19bn		EDIT-101	**Ocular** (Leber congenital amaurosis 10)	Phase I/II

Source: GlobalData Pharma Intelligence Center

மனித உடலின் கோடிக்கணக்கான செல்களும் உயிர்ப்போடு
இயங்க அனைத்து உயிர்ச்சத்துக்களும் தேவை

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எளிதில் எடுத்துச் செல்ல அழகிய கண்டெயினரில் கிடைக்கிறது.

(மருத்துவர் ஆலோசனைப்படி எடுத்துக் கொள்ளவும்)

...நீரில் இடவும்...

...கலக்கவும்...

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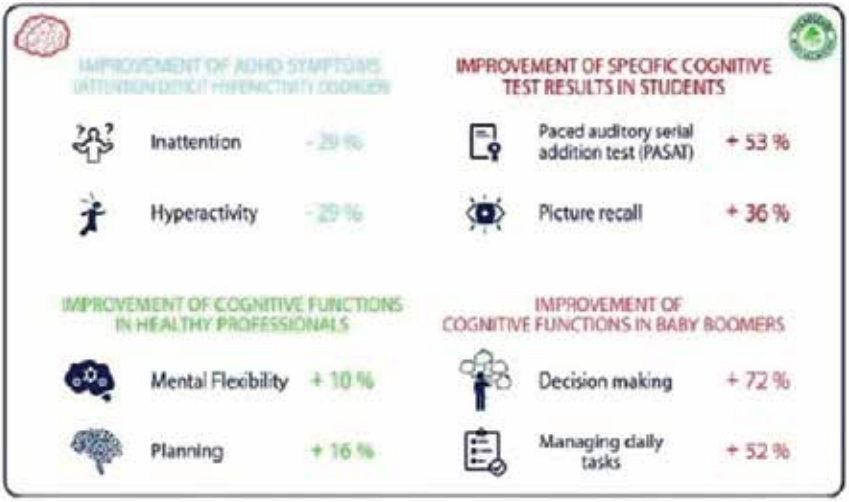
Drop ▶ Fizz ▶ Drink

LEKSHA

Pycnogenol® for cognitive function at every stage of life

Franziska Weichmann, Manager of Scientific Communications and Product Development, HORPHAG informs that Pycnogenol®has shown a broad spectrum of cognitive related benefits in all age groups and the underlying mechanism of action is based on its ability to regulate the endothelial function via adjusting nitric oxide (NO) production



A normal cognitive function is a prerequisite for a healthy life. The brain function may be altered in case of either hyperactivity or hypo-activity of the brain. Hyperactivity is frequently observed in children, commonly referred to as Attention Deficit Hyperactivity Disorder (ADHD), whereas the decline of brain activity is related to the aging process.

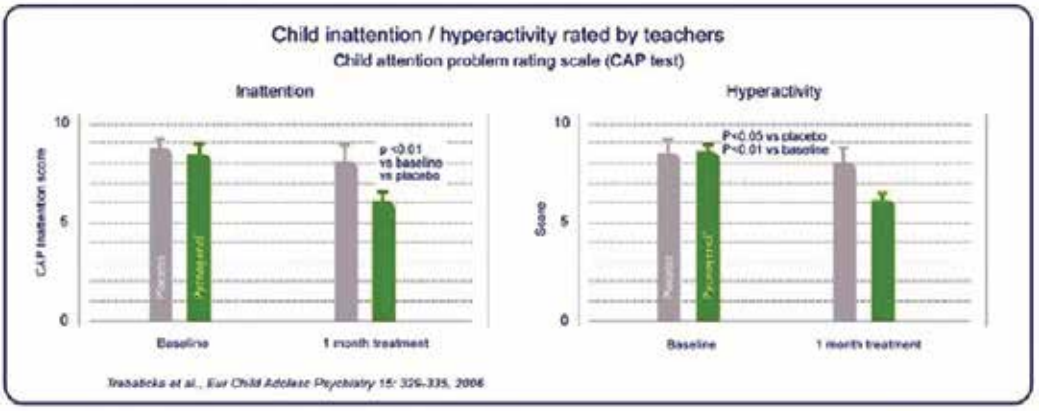
Remarkably, Pycnogenol French maritime pine bark extract has shown a broad spectrum of cognitive related benefits in all age groups. These benefits range from reducing hyperactivity in children (1-3) to improving cognitive function in students, healthy adults and elderly people (4-9).

Pycnogenol regulates cellular NO concentration, which affects brain function

The underlying mechanism of action of Pycnogenol® is based on its ability to regulate endothelial function via adjusting nitric oxide (NO) production (10, 11). It has been shown that NO has beneficial effects on brain function (12). NO is capable of relaxing constricted blood vessels, normalising blood pressure and helping to protect tissues from damage, caused by low blood supply (13). By regulating vascular smooth muscle relaxation, NO leads to increased blood flow, which ensures sufficient supply of oxygen to neuronal cells (14). In addition, NO has been found to regulate neuronal functions and helps to modulate key neurotransmitters, thus contributing to processing signals in the brain (15, 16). Interestingly, the active metabolites of Pycnogenol® build up inside the endothelial blood cells and have been proven to pass the blood-brain barrier (11).

Pycnogenol® regulates the NO production in two ways. The endothelial NO synthase (eNOS), generating normal concentrations of NO from L-arginine in the cell, is stimulated by Pycnogenol®. At the same time, Pycnogenol® prevents a toxic overproduction of NO by downregulating the inducible NO synthase (iNOS) – a well-established source of nitric oxide (NO*) during inflammation (11, 17). In this way, Pycnogenol® naturally modulates the multiple effects of NO in the brain.

Improvement of ADHD symptoms in children



ADHD (attention deficit hyperactivity disorder) is a frequent brain hyperactivity disorder, mainly affecting children. A common medication for this condition is Methylphenidate (Ritalin), but it is associated with various adverse effects (18). A double-blind, randomized, placebo-controlled clinical study could show that intake of Pycnogenol® (1 mg per kg and day) for four weeks relieved hyperactivity and improved attention of children with ADHD by 29 per cent respectively, as rated by teachers and parents (1). No side effects were reported. Another study investigated the levels of stress hormones (catecholamines) after Pycnogenol® supplementation in ADHD affected children (2). The concentrations of this group of hormones (including adrenaline, noradrenaline, and dopamine) were normalised in ADHD patients with Pycnogenol® supplementation, which consequently leads to less hyperactivity. Oxidative stress (measured conversely as plasma total antioxidant status) and DNA damage incidents (as measured by the levels of 8-oxoG as representative of oxidatively damaged purines) were significantly reduced by 6.3 per cent and 35.4 per cent respectively.

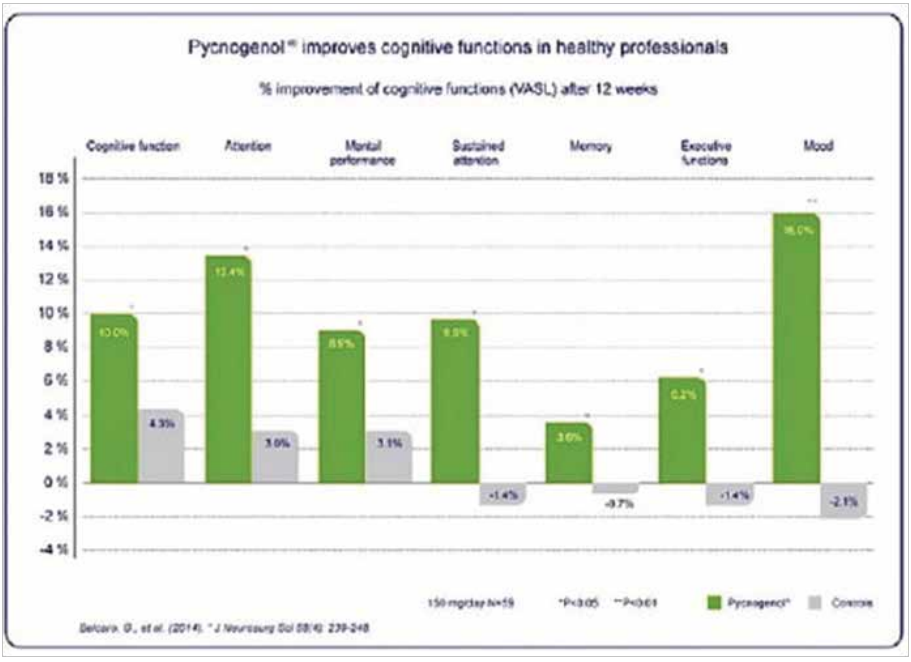
Enhanced mental performance in students

In an observational study, 53 healthy students, aged 18 to 27 years were supplemented with 100 mg Pycnogenol® a day for 8 weeks; another group of 55 students was used as control subjects (4). The effects of Pycnogenol® on cognitive function and mental performance were investigated, using different tests. For example, the paced auditory serial addition task (PASAT) was used for assessing sustained attention. For evaluating spatial recognition and working memory abilities, CANTAB (Cambridge neuropsychological test automated battery) was applied. The students showed significantly improved attention (+52.9% vs +4.7% in the control group) and increased memory skills (+35.8% vs +11.6% for picture recall, +6.7% vs. 2.6% for spatial recognition memory and +4.4% vs +3.5% for pattern recognition memory). Consequently, the test results of the supplemented students were better by 7.6% compared to the ones from the control group. Pycnogenol® was shown to have beneficial effects on the mental performance of healthy students.

Advanced cognitive function in healthy professionals

Another study, including 60 subjects between 35 and 55 years evaluated the effects of Pycnogenol® 150 mg a day on cognitive function, attention and mental performance in healthy professionals (5). For this, cognitive battery tests, similar to those of the previous study with students were used, determining, among other things, improvements in spatial working memory (+13.5%), planning (+16%), mental flexibility (ID/ED) (+9.8%) and general cognitive function (10%). No significant changes were found in the control group.

Additionally, the plasma oxidative stress levels were measured (as plasma free radicals in Carr units) and showed to be elevated at the beginning of the study, probably due to negative daily stress. After 12 weeks of supplementation with Pycnogenol®, a significant decrease of 30.4% to normal levels compared to a slight increase in the control group of 0.8% was measured.for picture recall, +6.7% vs. 2.6% for spatial recognition memory and +4.4% vs +3.5% for pattern recognition memory). Consequently, the test results of the supplemented students were better by 7.6% compared to the ones from the control group. Pycnogenol® was shown to have beneficial effects on the mental performance of healthy students.



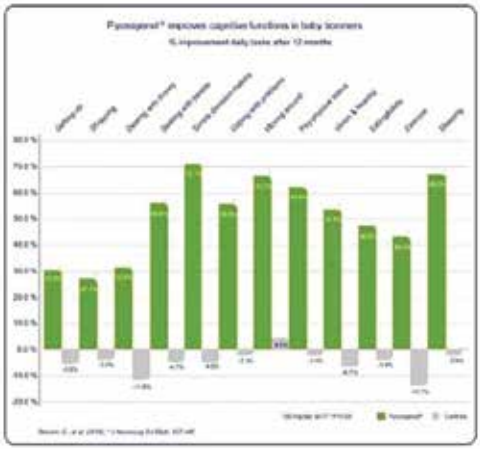
Improvement of cognitive function in the aging baby boomer generation

Neurological hypoactivity – the decline of brain activity – usually mainly affects aged or elderly people. This can result in senility, dementia or in diseases like Alzheimer's or Parkinson's disease. Here, the abilities to remember, recall, combine and orientate are deteriorating. A few studies have shown that Pycnogenol® can help to keep a good mental performance and to manage mild cognitive impairment (6-9). A study with 150 healthy subjects from 55 to 70 years, who were supplemented with 100 mg Pycnogenol® per day for 12 months confirms the beneficial effects of Pycnogenol® on healthy aging and the maintenance of good cognitive function (6). The tested parameters included cognitive impairment, attention, mental performance, memory, and daily tasks (like making decisions or coping with problems), all of which improved significantly in the supplementation group, in contrast to the control group. Another similar study with 87 subjects (55 to 75 years) with mild cognitive impairment showed several positive effects of Pycnogenol® supplementation (150 mg per day) for two months (7). The improvements were assessed using cognitive tests, as described before (regarding memory, attention, and daily tasks), as well as the MMSE (mini-mental state examination), which helps to evaluate borderline cognitive impairments for apparently unaffected individuals. The MMSE score increased significantly by 18.5% for the Pycnogenol® supplemented subjects, in contrast to an increase of 2.5% in the control group, bringing the MMSE score back to a normal level in the Pycnogenol® group. In a recent study on the effect of Pycnogenol® (150 mg per day) in patients with Parkinson's Disease, in addition to the standard medication with carbidopa/levodopa, beneficial effects could be observed in the supplement group after four weeks (8). The subjects, between 60 and 67 years old, described mild to moderate symptoms, including tremor, bradykinesia, alterations in cognitive function, rigidity, and speech changes. Using a scoring system, it was found that the cognitive function in these patients, supplemented with Pycnogenol® improved by 18.8% compared to inclusion. A double-blind, placebo-controlled trial with 101 subjects, between 60 and 85 with moderate decline of their cognitive function investigated the effects of 150 mg Pycnogenol® per day for three months on mental performance (9). The Australian study not only followed the cognitive abilities of the subjects but also the blood profiles, including the serum lipid profile and growth hormones. Statistically significant improvements, as compared to the placebo group could be found for memory-based cognitive functions, more precisely the

spatial and numeric working memory, and lipid peroxidation products, confirming Pycnogenol's role as a potent antioxidant. As impairment of the memory skills was connected to increased age and oxidative stress (19). These findings further support the beneficial effect of Pycnogenol® on cognitive functions in elderly people.

Population ageing generates a number of health concerns and maintaining a healthy cognitive function is of the utmost importance. Research shows Pycnogenol® and its unique properties can help improve cognitive health at all ages.

Pycnogenol French maritime pine bark extract is a safe, natural, and evidence-based solution to support a healthy cognitive function at any age. For a complete list of scientific research and for further information, please visit www.pycnogenol.com.



Our vision is to make pharma marketing effective and efficient

Doceree, a physician-only platform for programmatic marketing, is working towards building more effective ways for pharma brands to keep the doctors' community engaged. Dr Harshit Jain, Founder and CEO, Doceree outlines why it is important for pharma brands to redraw their doctor engagement strategies with the help of digital tools to reduce marketing costs, improve outcomes and ensure regulatory compliance, in an interview with Usha Sharma

Give us a brief understanding of Doceree? What is its USP?

Doceree is the global physician-only platforms for programmatic marketing. Our platform is disrupting the physician marketing landscape much in the same way digital ad networks transformed the consumer marketing space. Doceree's integrated and collaborative ecosystem enables pharmaceutical brands and digital platforms to mutually benefit from the untapped opportunities present in physician marketing in the most 'regulatory compliant and transparent manner'. Doceree is enabling Rx drug marketers to promote their brands in the digital domain to physicians in a regulated manner. At the same time, Doceree provides an opportunity for digital platforms to make more revenue. With our platform, they can now focus on their core business and the problems they are solving in healthcare than swaying their attention to making more monies. Effectiveness and efficiency are our prime differentiators that come from our razor-sharp focus on doctor-only platforms. Unlike other companies in the US where we have competition in programmatic physician marketing space, Doceree is focussing on doctor-only platforms for pharma brands to market themselves. Besides this, we are the only company in the category that has a global footprint with offices in the US and India. In India, we are the only programmatic platform in Physician marketing. The underlying thought is to ensure effectiveness. Our proprietary identity-resolution tool – Espyian – helps precision target physicians, bringing in efficiency to physician marketing.

In March 2020, the company raised funds of one million dollars? Tell us about the company's investment and future plans?

We raised $1 million in seed funding from a group of angel investors from India and the US in May 2020. As a business, our focus is on new market expansion and potential acquisition to realise our short term and long-term goals. In the short term, we want to become an ideal source of revenue generation for doctor-only digital platforms. In the long term, our goal is to reduce the cost of healthcare. We believe by introducing effectiveness and efficiency in pharma marketing, Doceree can reduce costs by about 10 per cent, which would eventually reflect upon the pricing of drugs.

How does your platform help pharma companies to reduce the cost of marketing activities without compromising the efficiency and effectiveness for physicians related to engagement activities?

Over the last decade, innovative digital business models emerged in a lot of sectors and helped companies reduce marketing costs significantly. However, pharma, by and large, remained an exception in opening up to digital mediums. The marketing approaches are still confined to traditional ways of doing business and physician marketing is nowhere close to consumer marketing that grew leaps and bounds after companies in the space switched to digital methods and made them an essential tool to reach out to their target audiences. This is where Doceree is making all the difference. It is enabling pharma brands to use digital technologies by addressing issues that have been acting as a roadblock in digital adoption among Rx drug brands.

Doceree is integrating doctor-only digital platforms not just in India but across the globe to create a unified and cohesive digital ecosystem. It is enabling pharma brands to target doctors at the right moment with the right message to be able to drive behaviour change and achieve desired business outcomes. It is also bringing transparency in 'doctor reach and results' through AI-enabled dashboard.

By being regulatory-compliant, our platform has reduced a lot of hassles related to regulations that pharma brands faced while partnering with individual digital platforms.

Although the government has not made UCPMP mandatory, there is a strong appeal for its implementation. What is your opinion on the same?

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How does your platform help pharma companies to reduce the cost of marketing activities without compromising the efficiency and effectiveness for physicians related to engagement activities?

In my capacity as a physician and a healthcare marketer, my personal view is that UCPMP shall be converted into law to bring more transparency and prevent any unethical promotion of pharmaceutical drugs and services. In the current form, it is not as effective as thought of. The profession of medicine is a system of faith and belief, and there must not be any means to sway the doctors' perceptions and lure them towards prescribing certain medicines, drugs or services. Pharma brands should reach out to doctors, share information about the efficacy of their products and leave it at that. Rather than push marketing, it should be pull marketing. If a doctor believes a drug to be efficient, he/she would take a call about prescribing it. What is important is that complete information should reach doctors and that too consistently so that it stays on top of their minds. Digital can be an amazing source for pharma brands to keep the doctors engaged, and there are digital platforms that are regulatory-compliant like Doceree that can help them achieve that objective. At this point in time, proper implementation of UCPMP will ensure everything remains in ethical ambit around marketing by pharma brands.

How will artificial intelligence and machine learning bring in a transformation in the pharma industry?

If we talk about the current scenario of AI and ML in Pharma, at best we can say that we're in a very early stage of adopting these technologies and how we're able to set our foundations will define the future for us. We are swimming in an ocean of data, or a better way to put it would be that we're drowning in it. Organisations and institutions are generating terabytes of data per day. AI and ML will help move from this data to critical information and insights. Even today, machines have replaced humans in healthcare and pharma sector, be it recognition of cancer cells using MRI/CT scan machines or regression models to predict diabetes in patients, health tech is evolving day by day and will continue to do so to stay one step ahead of the limitations of current systems being hit every day.

The new normal post-COVID-19 will see changes in pharma marketing. How will your platform leverage the opportunity and help the industry to strive for growth?

Our vision is to make pharma marketing effective and efficient. To achieve our mission, we are introducing new product features that aim at providing Rx drug brands with the control and the ability to optimise for better efficiencies. Recently, we launched two features:

(1) Integrated Programmatic Email Ad-serving Solution for Physicians, a product that brings in huge credibility in email marketing and promises to significantly enhance the performance of email campaigns.

(2) An AI-enabled dashboard ensures our clients – pharma brands and media agencies – get reports and updates about their campaigns in real-time. We are on the mission to address the issues that mark the adoption of digital by pharma brands globally and not just in one or two markets and to achieve our goals, we will keep evolving to serve advertisers and publishers in the best possible manner.

How will this change the landscape in pharma marketing, which is continuously evolving?

The pandemic has accelerated adoption of digital among Rx drug brands. I see extensive use of digital technologies going forward for marketing purposes as it is now an essential tool to reach out to the target audiences. The outbreak has certainly given a fair taste to pharma brands about how important digital tools are. Having gained from the experiences from the current situation, pharma brands will now be far more receptive to digital means.

Sanofi, Regeneron's Libtayo looks for new cervical cancer use with first-in-class survival win

Sanofi and Regeneron tout a first-in-class win showing their PD-1 inhibitor Libtayo could extend the lives over chemotherapy among patients with previously treated ovarian cancer. (Sanofi Genzyme/Regeneron)

As a latecomer to the PD-1/L1 game, Sanofi and Regeneron have been angling Libtayo toward some niche indications where it can grow freely, unhindered by competition. But now, the pair has recorded a clinical win in cervical cancer that megablockbuster early entrants can't tout.

Libtayo monotherapy significantly reduced the risk of death by 31% over chemotherapy in recurrent or metastatic cervical cancer that had progressed on platinum-based chemo, Sanofi and Regeneron said Monday. The drug helped patients live longer regardless of their tumors' PD-L1 biomarker status.

The two companies were quick to point out that the phase 3 overall survival win marked the first for an immuno-oncology agent in cervical cancer. Regulatory filings are planned for 2021 and exact results will be shared at a medical meeting, they said.

The good news came early after an independent data monitoring committee noted positive survival outcomes at an interim analysis. In the overall trial population, Libtayo patients lived a median 12 months versus 8.5 months among chemotherapy patients.

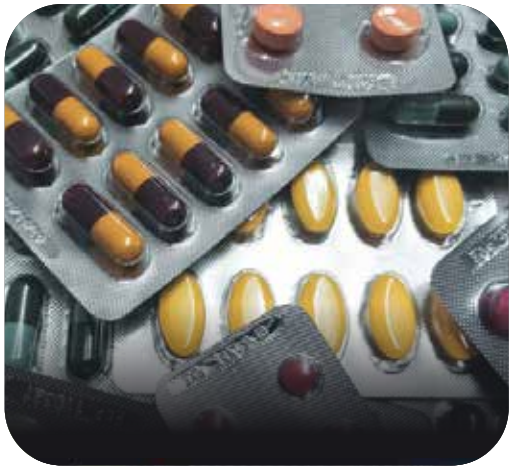
On the other co-primary endpoint of the study, the PD-1 inhibitor slashed the risk of death by 27% in a subgroup of patients with squamous cell carcinoma, as Libtayo patients lived a median 11.1 months, compared with 8.8 months in the chemo group. The squamous cell subtype constitutes 80% of all cervical cancer cases.

Merck & Co.'s Keytruda was the first I-O med to enter the cervical cancer field. Its conditional nod, limited to previously treated patients whose tumors express PD-L1, was based on tumor shrinkage and duration of response data.

Bristol Myers Squibb's Opdivo, both by itself and with CTLA4 inhibitor Yervoy, did show promising results in the phase 1/2 Check-Mate-358 trial with what the study lead investigator called "striking" overall survival curves for the dual I-O regimen, according to results unveiled at the ESMO 2019 meeting.

Sanofi and Regeneron may be the first to tout an important life-extension benefit in second-line cervical cancer, but it's entering a relatively small and dwindling market. In the U.S., 14,500 new patients are diagnosed with cervical cancer each year, the pair pointed out. As the CDC notes, the number of cases of cervical cancer has been decreasing significantly in the past few decades, partly thanks to the success of Merck's HPV vaccine Gardasil 9 and partly due to early screening efforts that can catch precancer before it turns into cancer. Almost all cervical cancer cases are caused by HPV infection.

If eventually approved, second-line cervical cancer could be Libtayo's fourth U.S. indication. Last month, the drug added newly diagnosed PD-L1-high non-small cell lung cancer to its label, jostling for a place in a lucrative market where Merck's Keytruda-chemo combo has established as the standard of care. Before that, Libtayo's green-lighted in two skin cancers, basal cell carcinoma and cutaneous squamous cell carcinoma.



Telangana government collaborates with Cytiva to establish new lab for biopharma

A Fast Trak lab will be established in the Genome Valley for Biopharma scale up, professional training, technology evaluation, consultancy services and infrastructure support for process development

Cytiva, a life science company, and the State of Telangana in India will work together to open a new Fast Trak lab in Hyderabad.

"The 10,000 sq ft lab, to be located in the Genome Valley, will accelerate and advance the local biopharma scale up needs. With over 800 life sciences companies nearby, the new facility will help the area's biotechnology hub increase production efficiency, reduce cost and speed to market," informed a statement from the company.

The State of Telangana has a rich mix of global pharma companies, Indian local biopharma giants, and biotech startups. Combined, they contribute about 35 per cent of India's pharma production. Cytiva's Fast Trak lab is expected to meet the area's fast-growing demand.

Vaggu Raghavendra Goud, General Manager of Cytiva South Asia, said, "Cytiva has been growing alongside the Indian biotechnology industry for more than 30 years. A Fast Trak lab brings us closer to our customers in one of the world's key biotechnology hubs. This partnership enables us to share our global knowledge and expertise at a regional level. It is a new milestone in our continued investment in the India market and another way we fully support the growth of the industry here."

Shakti Nagappan, Director of Life Sciences and Pharma, the State Government of Telangana, said, "The government of Telangana has conceptualized Biopharma-Hub (B-Hub) as a Growth Phase Park to provide necessary support to young companies graduating from incubation stage along with this biopharma scale-up manufacturing facility of about 200L to help companies produce clinical material (phase 1 & 2). The scale-up facility will also provide training, which is a key requirement to facilitate the growth of biosimilars in the life sciences industry. We are happy to partner with Cytiva for this."

24 new drugs developed with researches at CCRAS: Minister

ICAR-DMAPR is also focusing on researches and plant genetic resources/ quality planting material

Researches undertaken at the Central Council for Research in Ayurvedic Sciences (CCRAS) have helped in developing 24 new drugs, the government told the Rajya Sabha on Tuesday.

In a written reply, the Union Minister Kiren Rijiju said that the Ministry of AYUSH under its central sector scheme for promotion of International Cooperation (IC) undertakes various measures to promote and propagate AYUSH systems of medicine, including ayurveda, across the globe.

"... researches undertaken at Central Council for Research in Ayurvedic Sciences under Ministry of AYUSH has developed 24 new drugs. In addition, Council of Scientific & Industrial

Research (CSIR) has developed herbal formulations by their supported researches at CSIR-CIMAP, CSIR-NBRI and CSIR-CDRI and technology has been transferred to industry for its commercialisation," the minister said.

He was responding to a query by Rajya Sabha member M V Shreyams Kumar on whether the researches have helped in developing new medicines in Ayurveda.

Rijiju, who is holding the additional charge of the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy — said that ICAR-DMAPR is also focusing on researches and plant genetic resources/ quality planting material.

LupinLife launches Ayurvedic energy supplement, Be One

It is a natural, non-addictive and steroid-free daily health supplement for men

LupinLife, consumer healthcare business of Lupin, announced the launch of a new ayurvedic energy supplement for men, Be One. "Be One is a 100% Ayurvedic health and wellness supplement specially developed for men to help them stay energised and healthy. It is scientifically tested and contains 100% ayurvedic natural ingredients including ashwagandha, shatavari and shilajit that boost energy levels and improve immunity. Ministry of Ayush has recognised ashwagandha and pippali for their immunomodulatory properties. Additionally, both are also recognised as ingredients for building immunity by National Clinical Management Protocol for COVID-19," informed a company release.

Commenting on the launch, Rajeev Sibal, President, India Region Formulations, Lupin said, "We are delighted to launch Be One, an ayurvedic energy and immunity supplement, specially developed for men to take care of their daily energy and immunity needs. The supplement contains natural ingredients and powerful adaptogens to boost energy levels and restore vitality."

"We believe good health is the foundation for happiness and therefore, we are excited to launch Be One for men as a health and wellness enabler," said Anil V Kaushal, Head of LupinLife Consumer Healthcare.

Don't fret, AstraZeneca investors. The company is much more than a COVID vaccine producer, analysts say

AstraZeneca may be suffering a whirlwind of negative COVID-19 vaccine headlines now, but better days are ahead, thanks in part to a "prolific pipeline" and a strong oncology franchise.

That's the word from Jefferies analysts, who totted up reasons for their fair-weather forecast in a Tuesday investor note. Astra Zeneca is on an "impressive revenue and profit trajectory" that's "compelling" compared with other large European pharma companies, the analysts wrote.

While AstraZeneca is just setting out with its COVID-19 vaccine rollout—and obviously suffering the growing pains of a newcomer to the vaccine field—the company has spent years developing its oncology franchise. Those meds are set to deliver megabillions to AZ's top line, the analysts predict. Tagrisso alone is expected to peak at more than $10 billion in EGFR-positive lung cancer, including a potential $3 billion to $4 billion in adjuvant non-small cell lung cancer. The analysts see another $5.5 billion for PARP inhibitor Lynparza on the heels of a recent trial win in a subset of breast cancer patients. Immuno-oncology agent Imfinzi, for its part, is "likely entrenched" in stage III lung cancer, the analysts say, with applications in other tumors. Meanwhile, AstraZeneca in December agreed to buy rare disease drugmaker Alexion for $39 billion. The deal is expected to close in the third quarter, and around that time, the analysts predict the market better appreciate the deal's "strategic merit." The purchase will give AstraZeneca an entrée into rare diseases, plus chances to grow sales in different countries and to fund more R&D programs, they wrote.

Aside from marketed meds and the Alexion buy, a "multitude of pipeline catalysts" could boost AZ in the years to come, Jefferies analysts wrote. Those include other oncology candidates,

plus roxadustat in anemia from chronic kidney disease, anifrolumab in lupus and tezepelumab in asthma.

Plus, the company is the "best positioned" among European pharma companies to benefit from China's healthcare reforms, the analysts figure. AZ already has 15 medicines on the country's essential drugs list.

On the COVID-19 vaccine front, AstraZeneca's rollout has run into numerous problems, including supply shortfalls and regulators halting vaccinations over blood-clotting concerns. While those issues are commanding headlines, the analysts don't see COVID-19 vaccine revenues as a long-term fixture for the company.

They project $1 billion in COVID-19 vaccine sales this year, falling to a "negligible contribution" in 2024 and beyond.

Plus, in a bad-news-can-be-good-news assessment, the analysts figure investors may soon have a buying opportunity when forthcoming COVID-19 vaccine data are released.

Because of the company's phase 3 trial protocol in the U.S., weak data could force the stock lower, giving investors a chance to pick up AZ shares on the cheap, the analysts wrote. The U.S. study is using a "sub-optimal" 4-week dosing schedule, while "it has already been shown that the vaccine works better with a longer dosing interval," the Jefferies analysts wrote.

Challenging AbbVie and Lilly in psoriatic arthritis, J&J touts 2-year data for Tremfya

When Johnson & Johnson scored approval for Tremfya in psoriatic arthritis last year, the company set out in crowded field with entrenched competition. But now the drugmaker has new long-term data to bolster its drug's case.

In data from an extended phase 3 trial, more than half of adults on Tremfya achieved complete skin clearance at two years, J&J said. More than 70% of patients achieved 20% improvement or better in joint symptoms. Previously, the drug showed benefits through 24 weeks—leading to an FDA approval last year—and through 52 weeks.

Specifically, among patients who had experienced clinically meaningful skin involvement at baseline, 59% of patients who received Tremfya every four weeks-and 53% of those who received the drug every eight weeks—experienced complete skin clearance, J&J said. About 90% of patients randomized to receive Tremfya in the study continued their treatment through 100 weeks, J&J said. Aside from the skin clearance and joint symptom effects, the two-year data confirmed earlier findings demonstrating the med's benefits to physical function and other quality-of-life factors, J&J said.

The results "further bolster our confidence in the ability of Tremfya to significantly improve the diverse manifestations of PsA over time," Janssen R&D rheumatology disease area leader Alyssa Johnson said in a statement.Investigators are presenting the data at the Innovations in Dermatology virtual spring meeting.

The results give J&J a stepped-up talking point in a competitive field. When Tremfya won its FDA approval in psoriatic arthritis last year, the company set out to launch its drug against meds from AbbVie, Novartis and Eli Lilly. Plus, Lilly's Taltz boasts head-to-head data over the J&J drug. J&J's Tremfya, first approved in late 2017 to treat plaque psoriasis, generated $1.35 billion last year.

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