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Sun Pharma and Pharmazz Inc. enter into licensing agreement for introducing Tyvalzi™ (Sovateltide) in India

- Sovateltide is a first of its kind drug to treat acute cerebral ischemic stroke that can be administered up to 24 hours after the onset of symptoms
- India is the first global territory where Tyvalzi™ (Sovateltide) is being introduced

Mumbai, India, September 14, 2023: Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) today announced that one of its wholly-owned subsidiaries has entered into a license agreement with Pharmazz Inc., (Pharmazz), a U.S. based biopharmaceutical company to commercialise a first-in-class innovative drug, Tyvalzi™ (Sovateltide) in India. Developed by Pharmazz for potential global use, Sovateltide is indicated for treating cerebral ischemic stroke.

As per agreement terms, Sun Pharma is granted rights for marketing Sovateltide in India under the brand name Tyvalzi™ (Sovateltide). Pharmazz will be entitled to upfront and milestone payments, including royalties.

Kirti Ganorkar, CEO – India Business, Sun Pharma said, “The Phase 3 clinical trial for Tyvalzi™ conducted in India demonstrated statistically and clinically meaningful improvement in neurological outcomes in ischemic stroke. Tyvalzi™ is a first-in-class innovative drug which can help improve the quality of life of stroke patients. The drug can be administered within 24 hours for the treatment of ischemic stroke. The current treatment options provide a narrow time window of 4-5 hours limiting its use in most patients.”

Dr. B. S. Paul, a leading neuro-physician at Dayanand Medical College & Hospital, Ludhiana, who was a part of the clinical trials of Tyvalzi™ (Sovateltide), said, "No new drug other than rTPA has been approved for the treatment of stroke for more than two decades. The narrow time window of rTPA of 4.5 hours limits its use in a vast majority of patients with cerebral ischemic stroke. There is an urgent need for new therapies to treat stroke, the 2nd leading cause of mortality & morbidity worldwide. Sovateltide (Tyvalzi™), a selective endothelin B receptor agonist, a new first-in-class drug recently approved for treating cerebral ischemic stroke, can be administered up to 24 hours post cerebral ischemic stroke. Sovateltide (Tyvalzi™) produced statistically significant and clinically meaningful improvements in neurological outcomes at 90 days post-treatment in clinical trials as measured by the NIHSS, mRS, and B.I. scales. Sovateltide (Tyvalzi™) is a neuronal progenitor cell therapy that promotes neurogenesis, angiogenesis, and synaptogenesis, thereby inducing neurovascular remodeling. I believe that Sovateltide (Tyvalzi™) is an exciting new, approved, effective, and well-tolerated therapy for treating cerebral ischemic stroke patients. "

Dr. Prof. Anil Gulati, M.D., Ph.D., inventor, CEO, and Chairman of the Board of Directors of Pharmazz, said: "It is a significant step for Pharmazz to partner with Sun Pharma, the largest pharmaceutical company in India. For patients with cerebral ischemic stroke, I believe Sun Pharma



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is the best partner for Pharmazz to market Tyvalzi™ (Sovateltide), an innovative, first-in-class novel treatment for cerebral ischemic stroke, in India."

The global burden of disease project¹ estimated the number of incident cases of stroke in India to be 1,175,778. In India, studies estimate that the incidence of stroke population varies from 116 to 163 per 100,000 population². Stroke is the fourth leading cause of death and the fifth leading cause of disability³ in India. By 2050, more than 80% of the predicted global burden of new strokes of 15 million will occur in low and middle-income countries.

Sun Pharmaceutical is the owner of the brand name Tyvalzi™.

About Tyvalzi™ (Sovateltide)

Tyvalzi™ is a first-in-class drug to treat acute cerebral ischemic stroke, a condition in which the loss of blood supply to the brain prevents brain tissue from receiving oxygen and nutrients, resulting in potential brain damage, neurological deficits, or death. Tyvalzi™ is unique in that its site of action is the neural progenitor cells. Tyvalzi™ promotes neurovascular remodeling by forming new neurons (neurogenesis) and blood vessels (angiogenesis). Tyvalzi™ also protects neural mitochondria and enhances their biogenesis.

About Pharmazz, Inc.

Pharmazz is a privately held company engaged in developing novel products in critical care medicine. Pharmazz, Inc. obtained marketing authorization for two of its first-in-class drug molecules, Centhaquine and Sovateltide, for hypovolemic shock and ischemic stroke, respectively, in India. In addition, U.S. Food and Drug Administration (FDA) has approved two phase III INDs for Centhaquine as an agent for hypovolemic shock and Sovateltide for cerebral ischemic stroke. Additional information may be found on the Company's website, www.pharmazz.com.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generics company with presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India, and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, onco-dermatology and accounts for over 16% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

References:

1. *GBD 2016 Stroke Collaborators. Global, regional, and national burden of stroke, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2019; 48: 439–458.*
2. <https://main.mohfw.gov.in/organisation/Departments-of-Health-and-Family-Welfare/national-programme-prevention-and-control-cancer-diabetes-cardiovascular-disease-and-stroke-NPCDCS> (accessed on 28th August 2023)
3. *Directorate General of Health Services: Ministry of Health and Family Welfare. National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke. Government of India 2019, July 13, <https://main.mohfw.gov.in/Major-Programmes/non-communicable-diseases-injury-trauma/Non-Communicable-Disease-II/National-Programme-for-Prevention-and-Control-of-Cancer-Diabetes-Cardiovascular-diseases-and-stroke-NPCDCS> (2019, accessed 21 September 2020).*



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