

Sanofi launches 'once daily' oral tablet 'Aubagio[®]', for treatment of Multiple Sclerosis in India

- Aubagio[®] offers patients diagnosed with Multiple Sclerosis the efficacy and convenience of once-a-day oral treatment
- Over 200,000 people in India are living with Multiple Sclerosis¹

Mumbai, August 6, 2018: Sanofi Genzyme, the specialty care global business unit of Sanofi, brings to Aubagio[®], India from its international Multiple Sclerosis (MS) portfolio. A chronic and debilitating disease of the nervous system. Sclerosis Multiple has varied symptoms like weakness in the limbs, poor vision, fatigue or slurred speech.



Aubagio[®] (Teriflunomide, 14 mg) is the first original 'once-daily' oral 'disease modifying therapy' (DMT) for Multiple Sclerosis to be approved in India. It offers an effective, safe and a convenient option that is indicated as a first-line treatment for relapsing forms of Multiple Sclerosis that must be taken once a day, with or without food.

Commenting on the launch, **N. Rajaram, Managing Director, Sanofi** India said, "There are around two lakh people living with this disease in India. Increasingly, new cases are being detected due to greater awareness and access to better diagnostic facilities. For over a decade Sanofi has invested in developing and delivering novel therapeutic solutions for treatment of Multiple Sclerosis around the world; and is now bringing Aubagio®, our original research product to India."

He further added, "This product has the potential to offer an efficacious and convenient treatment regimen of just once a day oral tablet, vis-à-vis commonly available injectable treatment options. With Aubagio[®], we

¹http://www.mssocietyindia.org/: Accessed on July 4, 2018

⁽This was in the context of - Currently, in almost 90% cases , Multiple Sclerosis treatment is driven by injectables)

reaffirm Sanofi Genzyme's commitment to improve and empower the lives of people with debilitating diseases in India."

Dr. Shalini Menon, Country Medical Director, South Asia, Sanofi said, "Aubagio[®] is a differentiated disease modifying therapy, that blocks the enzyme involved in multiplication of overactive immune cells. When taken daily, Aubagio[®] reduces the number of overactive immune cells that cause the disease flare-ups, while still allowing normal immune cell activity to occur. It is important to note that Aubagio[®] has demonstrated consistent efficacy in reducing the frequency of relapses, delaying the progression of physical disability and, arresting further decrease in brain volume. In addition, since Aubagio[®] is an oral medicine, people with Multiple Sclerosis will find it very convenient and can continue with longterm treatment."

First approved by the US FDA in 2012, Aubagio[®] has a strong global presence today with approvals in more than 81 countries.³ It has been extensively studied in >5,500 patients with up to 13 years of clinical and follow-up studies with proven clinical efficacy, safety and tolerability outcomes.³ Globally >85,000 patients with Multiple Sclerosis are benefitting from the use of Aubagio^{® 3}.

About Multiple Sclerosis:

Multiple Sclerosis is an autoimmune, debilitating disease of the nervous system that affects the spinal cord and brain. In Multiple Sclerosis, there is progressive damage to the sheath that protects nerve cells, impairing communication between the brain and the nervous system. Signs and symptoms vary from one person to another and may include: weakness and numbness in the limbs, poor vision, tingling and pain in parts of the body, unsteady gait, lack of coordination, fatigue or slurred speech. Most people develop a 'relapsing-remitting' form of Multiple Sclerosis where symptoms ('relapses') may last for days or weeks and then improve completely or partially. This is then followed by a period of remission that could last for months or even years.²

Multiple Sclerosis is a common cause of disability that usually affects young persons during their most productive years but only 45% of all patients are correctly diagnosed.⁴

Research shows across the world, over 2.3 million people are living with Multiple Sclerosis.⁵

² Mayo Clinic. Multiple Sclerosis. Available at: <u>https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269?p=1</u> Accessed on May 24, 2018.

⁵ <u>http://www.msif.org/wp-content/uploads/2014/09/Atlas-of-MS.pdf</u>

About Aubagio®

Aubagio® is an innovator product with almost 13 years of proven clinical efficacy, safety and tolerability data, and is a best in class medication for relapsing and remitting Multiple Sclerosis. It is a differentiated Disease-Modifying Therapy (DMT), which works by blocking the enzyme needed for immune cells to keep multiplying at an overactive rate. When taken daily, Aubagio® reduces the number of overactive immune cells [that causes the disease flare-ups, while still allowing normal immune cell activity to occur]. Unlike other medicines, Aubagio® is India's first innovator 'once-daily' oral pill to treat Multiple Sclerosis in India. It can be taken any time of the day, with or without food. This ensures patient adherence and convenience, both of which are missing in currently available Multiple Sclerosis therapies.

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About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which

³ Genzyme data on File

⁴ Genzyme data on File (As per market research done in 2015)

are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.