



**FOR IMMEDIATE RELEASE**

## **Sun Pharma & Samsung BioLogics announce strategic manufacturing tie-up for Tildrakizumab**

**Mumbai, INDIA & Incheon, KOREA - July 04, 2017:** Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharmaceutical Industries Ltd" and includes its subsidiaries or associate companies) and Samsung BioLogics announced a strategic long-term manufacturing agreement for Tildrakizumab. The agreement was entered into by Sun Pharma's wholly-owned subsidiary and Samsung BioLogics. According to the agreement, Sun Pharma has appointed Samsung BioLogics to manufacture Tildrakizumab, an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate to severe plaque psoriasis. Filings for this novel investigational biologic has been accepted for review by the U.S. Food and Drug Administration (FDA) (May 2017) and the European Medicines Agency (EMA) (March 2017). The agreement was signed at Samsung BioLogics' headquarter in Incheon, South Korea. The approximate value of the contract will be US\$ 55.5 million, other financial details of the agreement are confidential.

**Commenting on the development, Dr. TH Kim, President and CEO of Samsung BioLogics said,** *"Samsung BioLogics is pleased to join hands with Sun Pharma and is looking forward to delivering best-in-class manufacturing services with global quality standards. Our collaboration with Sun Pharma is an important milestone for Samsung as it is a testament of our ability to provide reliable supply through its GMP-certified manufacturing facility to pharmaceutical companies, which aim to expand their global market."*

**Commenting on its agreement with Samsung BioLogics, Mr Kirti Ganorkar, Global Head – Portfolio Management & Business Development, Sun Pharma said,** *"Samsung BioLogics is a globally renowned CMO. Through this partnership we will leverage Samsung's manufacturing knowledge and world class quality systems to provide high quality products for the Tildrakizumab pipeline."*

### **About Tildrakizumab**

Tildrakizumab is an investigational humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this precise targeting, tildrakizumab has the potential to help control the pathogenic cells responsible for the inflammatory process of psoriasis with limited impact on the rest of the immune system. Phase-3 tildrakizumab data provide further evidence for the role of the IL-23 pathway in helping to control the inflammatory process of psoriasis. The regulatory filings associated with tildrakizumab have been accepted for review by the FDA and EMA.

### **About Sun Pharma, Merck & Co., Inc., Kenilworth, NJ, USA, Agreement**

Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary received worldwide rights to



tildrakizumab from Merck (through a Merck subsidiary), known as MSD outside the United States and Canada, in 2014. Funded by a Sun Pharma subsidiary, Merck is responsible for the completion of Phase- 3 trials in patients with mild-to-moderate plaque psoriasis and, as appropriate, submission of a Biologics License Application to the United States Food and Drug Administration (FDA). Merck is also responsible for manufacturing finished goods to support Sun Pharma's initial product launch. Post-approval in the U.S., Sun Pharma will be responsible for all other regulatory activities, including subsequent submissions, pharmacovigilance, post approval studies, manufacturing and commercialization of the approved product. Sun Pharma will also be responsible for all regulatory, pharmacovigilance, post approval studies, manufacturing and commercialization of approved products for all non-U.S. markets. Merck is eligible to receive milestone payments and royalties on sales of tildrakizumab.

**About Sun Pharma, Almirall S.A, Europe, Agreement**

Sun Pharma and its wholly owned subsidiary and Almirall (Spanish Stock Exchange ticker: ALM) closed on July 2016 a licensing agreement on the development and commercialization of tildrakizumab for psoriasis in Europe. Under terms of the license agreement, Almirall is able to lead European studies, and participate in larger Global clinical studies for psoriasis indication subject to the terms of the Sun Pharma – Merck agreements, as well as certain cost sharing agreements. Sun Pharma will be eligible to receive development and regulatory milestone payments and, additionally, sales milestone payments and royalties on net sales. Sun Pharma will continue to lead development of tildrakizumab for other indications, where Almirall will have right of first negotiation for certain indications in Europe. The agreement between Sun Pharma and Almirall remains subject to the exclusive license agreement between Sun Pharma and Merck.

**Disclaimer:**

*Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.*

**About Samsung BioLogics**

Samsung BioLogics is a global full-service provider of quality-driven contract process development and cGMP manufacturing to the global biopharmaceutical industry. Our facilities are custom designed for monoclonal & recombinant production with maximum flexibility. Our one-stop services include cell line generation, process and analytical method development, analytical services, clinical and commercial bulk cGMP manufacturing of drug substance and drug product including quality assurance, quality control, regulatory compliance standards & support for our customers. For additional information about the company, please visit <http://www.samsungbiologics.com>

**About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):**

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 42 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 11 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 3 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000



## SAMSUNG BIOLOGICS

scientists and R&D investments of approximately 8% of annual revenues. For further information please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live

### **Contacts: Sun Pharma**

#### **Media**

Frederick Castro

Tel +91 22 4324 4324, Xtn 2777

Tel Direct +91 22 4324 2777

Mobile +91 99206 65176

E mail [frederick.castro@sunpharma.com](mailto:frederick.castro@sunpharma.com)

#### **Investors**

Nimish Desai

Tel +91 22 4324 4324, Xtn 2778

Tel Direct +91 22 4324 2778

Mobile +91 98203 30182

E mail [nimish.desai@sunpharma.com](mailto:nimish.desai@sunpharma.com)

### **Contacts: Samsung Biologics**

#### **Media**

I.Chan Hwang

Phone 82 32 455 9332

E mail [inchan.hwang@samsung.com](mailto:inchan.hwang@samsung.com)

#### **Investors**

Soyoung Chung

Phone 82 32 455 3796

E mail [soyoung.chung@samsung.com](mailto:soyoung.chung@samsung.com)