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Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents

Sep 8, 2017

The Tribe Is Filing Motion to Dismiss Inter Partes Review of RESTASIS Patents Based on its Sovereign Immunity

DUBLIN, IRELAND -September 8, 2017– Allergan plc (NYSE: AGN), a leading global pharmaceutical company, and the Saint Regis Mohawk Tribe today announced that the Tribe now owns all Orange Book-listed patents for RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05%, and that Allergan has been granted exclusive licenses in the patents related to the product. The Tribe, a recognized sovereign tribal government, is filing a motion to dismiss the ongoing *inter partes* review (IPR) of the RESTASIS® patents based on their sovereign immunity from IPR challenges. The agreement with the Tribe has no impact on the pending abbreviated new drug application (ANDA) patent litigations regarding the RESTASIS® patent family which recently completed a five-day trial in Federal District Court in Marshall, Texas.

"The Saint Regis Mohawk Tribe and its counsel approached Allergan with a sophisticated opportunity to strengthen the defense of our RESTASIS® intellectual property in the upcoming *inter partes* reviewproceedings before the Patent Trial and Appeal Board," said Bob Bailey, Allergan's Chief Legal Officer. "Allergan evaluated this approach closely, with expert counsel in patent and sovereign immunity law. This included a thorough review of recent case law such as *Covidien LP v. University of Florida Research Foundation Inc.* and *Neochord, Inc. v. University of Maryland*, in which the PTAB dismissed IPR proceedings against the universities based upon their claims of sovereign immunity. We are impressed with the Tribe's thoughtful and enterprising approach, which will allow them to achieve their goals of self-reliance and help them address the most urgent needs in their community."

In a unified statement about the agreement with Allergan, the Saint Regis Mohawk Tribal Council stated, "This is a viable and sound opportunity for the Saint Regis Mohawk Tribe to enter into the patent, technology and research sector as part of our overall economic diversification strategy. We realize that we cannot depend solely on casino revenues and, in order for us to be self-reliant, we must enter into diverse business sectors to address the chronically unmet needs of the Akwesasne community; such as housing, employment, education, healthcare, cultural and language preservation."

Under the terms of the agreement, the Tribe will receive \$13.75 million upon execution of the agreement. Additionally, the Tribe will be eligible to receive \$15 million in annual royalties.

The patents transferred to the Tribe include United States Patent Nos. 8,629,111; 8,633,162; 8,642,556; 8,648,048; 8,685,930 and 9,248,191. The patents are listed in the Orange Book for RESTASIS® and expire on August 27, 2024.



Find authenticated court documents without watermarks at docketalarm.com.

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model - Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. With this approach, Allergan has built one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs currently in development.

Allergan's success is powered by our more than 18,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at (http://www.allergan.com/)www.Allergan.com (http://www.Allergan.com).

About Saint Regis Mohawk Tribe:

The Saint Regis Mohawk Tribal Council is the duly elected and U.S. federally recognized government of the Saint Regis Mohawk People.

For more information, visit the Saint Regis Mohawk Tribe's website at (http://www.srmt-nsn.gov/)www.srmt-nsn.gov (http://www.srmt-nsn.gov).

Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective on existing trends and information as of the date of this release. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2016 and Allergan's Quarterly Report on Form 10-Q for the period ended June 30, 2017. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

Office Of Technology Research And Patents FAQS (https://www.srmt-nsn.gov/ uploads/site files/Office-of-Technology-Research-and-Patents-FAQs.pdf)

Working Together Today to Build a Better Tomorrow

Ska'tne ionkwaio'te ón:wa wenhniserá:te ne sén:ha aioianerénhake ne enióhrhen'ne



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