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Bayer HealthCare AG And Regeneron Pharmaceuticals, Inc. To Collaborate On VEGF Trap For The Treatment Of Eye Diseases; Regeneron Retains U.S. Commercialization Rights, Receives \$75 Million Upfront, And Eligible For Up To \$245 Million Of Milestone Payments

Published: Oct 19, 2006

LEVERKUSEN, Germany and TARRYTOWN, N.Y., Oct. 18 /PRNewswire-FirstCall/ -- Bayer HealthCare (NYSE: BAY - News) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN - News) today announced that the companies have entered into a collaboration agreement for the global development, and commercialization outside the U.S., of the VEGF Trap for the treatment of eye disease by local administration (VEGF Trap-Eye). The VEGF Trap-Eye, currently in Phase I and Phase II clinical trials, is a protein that binds to or "traps" vascular endothelial growth factor (VEGF) and blocks its activity. VEGF is thought to play a critical role in certain eye diseases.

<https://www.biospace.com/article/releases/bayer-healthcare-ag-and-regeneron-pharmaceuticals-inc-to-collaborate-on-vegf-trap-for-the-treatment-of-eye-diseases-b-regeneron>

Bayer HealthCare AG And Regeneron Pharmaceuticals, Inc. To Collaborate On VEGF Trap For The Treatment Of Eye Diseases; Regeneron Ret

"The VEGF Trap is an excellent strategic fit for Bayer, which underscores our commitment to specialty pharmaceuticals," said Arthur Higgins, Chairman of the Board of Management, Bayer HealthCare. "We are encouraged by the early clinical data we've seen and believe the VEGF Trap has the potential to further transform the treatment paradigm for patients suffering from diseases of the eye."

Under the agreement, Bayer and Regeneron will collaborate on the development of the VEGF Trap-Eye through an integrated global plan that encompasses the neovascular form of age-related macular degeneration (wet AMD), diabetic eye diseases, and other eye diseases and disorders. The companies will jointly commercialize the VEGF Trap-Eye outside the U.S and will share equally in profits from ex-U.S. sales. Within the U.S., Regeneron has exclusive commercialization rights in all indications and will retain 100% of all profits from any such sales.

Principal financial terms of the agreement include:

* Bayer will make an upfront payment of \$75 million to Regeneron.

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* Bayer and Regeneron will share initial global development costs (totaling over \$250 million over the next several years) as follows:

-- 2007-2008: According to a formula based on total development costs

-- 2009 and thereafter: All expenses shared equally.

* If a VEGF Trap-Eye product is granted marketing authorization in a major market country outside the U.S., Regeneron, from its 50% share of VEGF Trap-Eye profits outside the U.S., will reimburse Bayer for 50% of the development costs that Bayer has incurred.

* Regeneron can earn up to \$110 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye for wet AMD and DME (or other major eye indications) and marketing approvals in a major market countries outside the U.S. A total of \$40 million of these milestone payments are due upon the initiation of Phase 3 clinical trials in wet AMD and diabetic macular edema (DME).

* Regeneron can earn up to \$135 million in sales milestones when total annual sales of the VEGF Trap-Eye outside the U.S. achieve certain specified levels starting at \$200 million.

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"As an established leader in specialty pharmaceutical products, Bayer is an ideal partner to help develop and commercialize the VEGF Trap outside the U.S. for eye disease," said Leonard S. Schleifer, M.D., Ph.D., president and chief executive officer of Regeneron. "In recent years there have been important advances in the treatment of serious eye diseases such as wet AMD, which is the leading cause of vision loss and blindness among people over age 65. However, there continues to be a need for additional treatment options. We look forward to working together with Bayer to aggressively develop the VEGF Trap-Eye for wet AMD, diabetic eye disease, and other eye diseases with unmet medical needs."

About Wet AMD and the VEGF Trap-Eye

Age-related Macular Degeneration (AMD) and diabetes are the leading non- infectious causes of acquired blindness. Patients with these conditions can experience a gradual loss of vision due to the development of abnormal, fragile new blood vessels in the back of the eye. There is a particular type of AMD called "wet AMD" which accounts for approximately 90% of AMD-related blindness, despite constituting only 10% of cases of AMD. Approximately 1.5 million people are affected with wet

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AMD in the United States and at least an equal number in the rest of the world.

The development of the blood vessels which contribute to these conditions is in part due to a secreted protein called Vascular Endothelial Growth Factor, or VEGF. VEGF is a naturally occurring protein in the body whose normal role is to trigger formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye, which lead to the development of a number of eye diseases, such as wet AMD.

The VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A and related placental growth factor (PlGF). The VEGF Trap-Eye is designed to block the interaction of these growth factors with cell-surface receptors, thereby preventing the subsequent formation of the new blood vessels that play an important role in the development of eye diseases such as wet AMD.

Currently the VEGF Trap is in a Phase II clinical trial for the treatment of patients with wet AMD and a Phase I trial for the treatment of patients with diabetic macular edema (DME).

About Regeneron Pharmaceuticals

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