

ThromboGenics Announces FDA Acceptance of Investigational New Drug (IND) Application for Phase II Study with JETREA® for the Treatment of Non-Proliferative Diabetic Retinopathy (CIRCLE)

Leuven, Belgium – 12 November 2015 - ThromboGenics NV (Euronext Brussels: THR), an integrated biopharmaceutical company focused on developing and commercializing innovative medicines for the treatment of vitreo-retinal disorders, today announces that the FDA has accepted its Investigational New Drug (IND) Application for its CIRCLE study, a Phase II, randomized, double-masked, sham-controlled, multi-center study that will evaluate the efficacy and safety of multiple doses of ocriplasmin in inducing total posterior vitreous detachment (PVD) in subjects with non-proliferative diabetic retinopathy (NPDR).

CIRCLE will evaluate JETREA® for the treatment of patients with moderately to very severe NPDR and its potential to reduce their risk of progression to Proliferative Diabetic Retinopathy (PDR). The phase II study will be conducted in clinical sites in the United States as well as in several European countries.

ThromboGenics and its clinical advisors believe that by using JETREA® to generate a PVD, the development of PDR and its sequelae may be prevented. PVD induction eliminates the scaffold for which new blood vessels may bleed into the vitreous. This belief is reinforced by the fact that the complications of PDR are less in patients who have a PVD.

A recent report from the American Academy of Ophthalmology has projected that the prevalence of individuals with vision threatening diabetic retinopathy in the United States will be around 1.34 million persons by 2020.

ThromboGenics remains on track to recruit the first patient in the United States around year-end 2015.

Dr Patrik De Haes, ThromboGenics' CEO, said: "The FDA acceptance of our IND is a key step in our plans to develop JETREA® for patients with diabetic retinopathy, a very significant indication where there is a clear need for improved treatment options and where we believe this novel medicine can meet a major unmet medical need. Today's FDA news also allows us to reconfirm that our Phase II CIRCLE trial in this indication remains on track to initiate around year-end."

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About ThromboGenics

ThromboGenics is an integrated biopharmaceutical company focused on developing and commercializing innovative treatments for diabetic eye disease.

The Company's first product, JETREA[®] (ocriplasmin), has been approved in 53 countries across the globe. In the US, ThromboGenics is commercializing JETREA[®] via its subsidiary ThromboGenics Inc. ThromboGenics signed an agreement with Alcon, a division of Novartis, for the commercialization of JETREA[®] outside the United States.

ThromboGenics is planning the CIRCLE study, a Phase II clinical trial with JETREA[®] in diabetic retinopathy and expects to recruit the first patient into the study around the end of 2015. In addition to JETREA[®], the Company is evaluating several other drug candidates that could potentially deliver a number of next generation treatments for eye disease.

ThromboGenics is headquartered in Leuven, Belgium, and has offices in Iselin, NJ (US) and Dublin, Ireland. The Company is listed on the NYSE Euronext Brussels exchange under the symbol THR. More information is available at www.thrombogenerics.com.

About JETREA[®] (ocriplasmin)

JETREA[®] (ocriplasmin) is a truncated form of human plasmin. JETREA[®] acts as a selective proteolytic enzyme that cleaves fibronectin, laminin and collagen, three major components of the vitreoretinal interface that play an important role in vitreomacular adhesion.

In the US, JETREA[®] is indicated for the treatment of symptomatic vitreomacular adhesion. In Europe, JETREA[®] is indicated for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns.

JETREA[®] was evaluated in two multi-center, randomized, double-masked Phase III trials conducted in the U.S. and Europe involving 652 patients with vitreomacular adhesion. Both studies met the primary endpoint of resolution of VMA at day 28. This Phase III program found that 26.5% of patients treated with ocriplasmin saw resolution of VMA, compared with 10.1% of patients receiving placebo ($p < 0.01$). The Phase III program also showed that JETREA(R) was generally well tolerated with most adverse events being transient and mild in severity.

In March 2015, ThromboGenics reported top line results from OASIS, a Phase IIIb study. This randomized, sham controlled, double masked study followed-up patients for 24 months post injection. In this study, retina physicians were able to use SD-OCT to select patients with focal VMA and without Epiretinal Membrane (ERM), two criteria which have been shown to lead to better treatment outcomes with JETREA[®]. Despite this, OASIS data showed over 20% of the patients recruited into study had ERM.

The trial showed that 41.7% of patients treated with JETREA[®] achieved VMA resolution at Day 28 post injection compared with only 6.2% of patients who received a sham injection ($p < 0.001$); and that the drug's safety profile in the 24-month follow period was consistent with the drug's overall safety profile as known from the approved label.

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and



uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report.

This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of ThromboGenics in any jurisdiction. No securities of ThromboGenics may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.