

*Press release*

**ThromboGenics Reports Day 150 Topline Data from its Phase 1/2 Clinical Study evaluating THR-317 (anti-PlGF) for the Treatment of Diabetic Macular Edema (DME)**

**Study results confirm safety and tolerability of THR-317 for intra-ocular use, and show improvement in visual acuity for up to 90 days after last injection**

**Leuven, Belgium, 19 July 2018** – ThromboGenics NV (Euronext Brussels: THR), a biotechnology company developing novel medicines for back of the eye diseases focused on diabetic eye conditions, reports Day 150 topline results from a Phase 1/2, single-masked, multicentre study (THR-317-001) evaluating the safety and efficacy of 2 dose levels (4 mg and 8 mg) of THR-317, administered by three monthly intravitreal injections with Day 90 and Day 150 follow-up, for the treatment of diabetic macular edema (NCT03071068).

THR-317 is a recombinant humanized monoclonal antibody directed against the receptor-binding site of human placental growth factor (PlGF). In pre-clinical models, anti-PlGF has been shown, in addition to anti-angiogenic properties, to also be anti-inflammatory.

The THR-317-001 study enrolled a total of 49 patients and included anti-VEGF treatment naïve patients (N=40) and anti-VEGF sub-optimal responder patients (N=9).

The study met its primary endpoint of safety for both the 4 mg and 8 mg doses. There was a low incidence of ocular adverse events, which were mostly mild and related to the injection procedure.

Whilst the focus of the study was safety, efficacy was also observed. Overall, patients receiving the 8mg dose of THR-317 achieved better visual acuity outcomes than in the 4mg dose group. Initial data reported for the 8mg anti-VEGF treatment naïve group at Day 90, 30 days after the last THR-317 injection, showed that 30% of patients achieved a  $\geq 15$  letter vision gain from baseline.

At Day 150, 90 days after the last injection, in the 8 mg anti-VEGF treatment naïve group, 30% of these patients showed  $\geq 10$  letter vision gain and 10% showed a  $\geq 15$  letter vision gain, supporting durability of effect.

In this 8mg group, average change from baseline in central subfield thickness showed a positive trend at Day 90, not observed at Day 150, which is 90 days after last injection.

The study also showed clinical activity in the THR-317 anti-VEGF sub-optimal responder group. Due to the small numbers in this group, no firm conclusions could be drawn.

Presentation of THR-317-001 study results is being planned for an upcoming ophthalmology meeting.

These data provide continued support to the development of THR-317. A Phase 2 study of 8mg THR-317 in combination with anti-VEGF (ranibizumab, Lucentis<sup>®</sup>) for the treatment of DME is currently enrolling.

**Susan Schneider, MD, Chief Medical Officer of ThromboGenics nv**, comments: *“We are excited about the development of THR-317 for the potential treatment of diabetic macular edema. Topline results from this study show strong safety data as well as first indications of clinical activity and durability of effect.”*

**Patrik De Haes, MD, Chief Executive Officer of ThromboGenics nv**, comments: *“These encouraging results provide first steps in the realization of our objective to deliver efficacious and differentiated treatments to patients with Diabetic Retinopathy by targeting novel therapeutic pathways. Different patient subpopulations will need different approaches in order to get their eye disease under control. It is our goal to serve the unmet needs of those patients.”*

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### **About THR-317 Phase 1/2 study**

A Phase 1/2, single-masked, multicentre study to evaluate the safety and efficacy of 2 dose levels of THR-317 for the treatment of diabetic macular edema (DME). It is the first clinical study to evaluate safety and efficacy of an anti-PIGF antibody for intravitreal use.

The study evaluated the safety of 3 monthly IVT injections of 2 dose levels of THR-317 (4 mg or 8 mg).

The study enrolled 40 anti-VEGF treatment naive patients, and 9 anti-VEGF sub-optimal responders.

## **About ThromboGenics**

ThromboGenics is a biopharmaceutical company focused on developing novel treatments for back of the eye diseases with an innovative pipeline in diabetic eye disease. The company's pipeline of disease modifying drug candidates is targeting the key segments of the diabetic eye disease market.

ThromboGenics' clinical pipeline consists of THR-317, a PIGF inhibitor, for the treatment of diabetic macular edema (DME), which is in an ongoing Phase 2 clinical study in combination with Lucentis<sup>®</sup>, and THR-149, a plasma kallikrein inhibitor which is in a Phase 1 clinical study for DME. THR-687 (an integrin antagonist) is in late-stage preclinical development for the treatment of diabetic retinopathy and DME. THR-687 is expected to enter the clinic in H2 of 2018. Further new drug candidates are currently being assessed and developed for the treatment of diabetic eye disease.

ThromboGenics owns the global rights to JETREA<sup>®</sup> (ocriplasmin), the only pharmacological vitreolysis drug approved for the treatment of symptomatic vitreomacular adhesion (in the US) and vitreomacular traction (outside the US).

ThromboGenics is headquartered in Leuven, Belgium, and is listed on the NYSE Euronext Brussels exchange under the symbol THR.

More information is available at [www.thrombogenics.com](http://www.thrombogenics.com)

### ***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.*