



GenSight Biologics announces the registration of its *document de base* in relation to its planned IPO on Euronext's regulated market in Paris

Paris, 25 May 2016 – GenSight Biologics, a biotechnology company discovering and developing novel gene therapies for neurodegenerative retinal diseases and diseases in the central nervous system, announces the registration of its *document de base* with the French *Autorité des Marchés Financiers* (AMF) under number I.16-049 on May 24, 2016 in relation to its planned IPO on Euronext's regulated market in Paris.

The registration of the *document de base* is the first step in GenSight Biologics' planned IPO on Euronext's regulated market in Paris, which is contingent on market conditions and regulatory requirements including the AMF's visa on a prospectus to be prepared as part of the transaction.

GenSight Biologics is developing two core technology platforms: Mitochondrial Targeting Sequence (MTS), and optogenetics. Out of a large number of applications, GenSight Biologics has chosen to initially focus on neurodegenerative retinal diseases. GenSight Biologics' product candidates GS010 and GS030 are designed to be administered in a single treatment to each eye by intravitreal injection, in order to offer patients a long-lasting functional cure.

GenSight Biologics' most advanced lead product candidate GS010 targets Leber Hereditary Optic Neuropathy (LHON) and is currently in Phase III. GS010 has received Orphan Drug designation in Europe and the United States. GenSight Biologics' MTS technology platform was originally developed by the teams of Pr. José Sahel at the Institut de la Vision in Paris and is protected by patents over which the company has acquired exclusive licenses in ophthalmology and non-exclusive licenses in other mitochondrial diseases. GenSight Biologics believes that its MTS technology platform can be used to address indications outside of ophthalmology involving defects of the mitochondrion.

GenSight Biologics' second product candidate, GS030, based on the optogenetics technology, is currently at the preclinical stage. The optogenetics technology confers light sensitivity to neurons, which allows to specifically stimulate targeted cells without affecting neighboring cells. GS030 is initially intended to treat all forms of genetic retinitis pigmentosa, and will subsequently target geographic atrophies, resulting from the late-stage form of age-related macular degeneration. GenSight Biologics is expected to initiate a Phase I/II clinical trial with GS030 during the second half of 2017, subject to the requirements of regulatory agencies.

"The IPO project is a significant new step in GenSight Biologics' development. Our lead product candidate GS010, currently in Phase III clinical trials, could be two years away from filing a regulatory approval for a marketing authorization from 2018 onwards. If the results from the ongoing clinical trials meet expectations, we could offer patients a treatment that should allow them to gain autonomy and benefit from an improved quality of life." commented Bernard Gilly, CEO of GenSight Biologics.

6 million patients suffer from blindness in Europe and North America. Based on data from regional studies, GenSight Biologics estimates the incidence of LHON to be approximately 1,400 to 1,500 new patients who lose their sight every year in the United States and Europe. RP is the most widespread hereditary cause of blindness in developed nations, with a prevalence of about 1.5 million people throughout the world.

Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease resulting in sudden irreversible vision loss for adolescents and young adults

LHON, targeted by GS010, is a rare mitochondrial genetic disease characterized by the degeneration of retinal ganglion cells that results in rapid, severe and irreversible vision loss, that can lead to complete blindness, and mainly affects adolescents and young adults. LHON alters the patients' ability to perform daily life activities, such as reading, driving, or facial recognition. Patients' autonomy is generally very limited, with a significant impact on their families, and substantial direct and indirect costs related to the management of this disability.

GS010: Promising clinical results...

In April 2015, GenSight Biologics completed the recruitment of 15 patients for its Phase I/II study to evaluate the safety and tolerability of GS010. The preliminary results on humans have demonstrated a good safety and tolerability profile.

Patients will be closely followed for a minimum of 3 years. Preliminary pharmacodynamics results at 48 weeks have demonstrated improvements in visual acuity and color perception for treated eyes, in patients with an onset of disease of less than 2 years. Improvements in visual field and color perception have also been observed in patients with the best preserved function before treatment.

Although the study was not designed to demonstrate efficacy of the treatment, due to the diversity of doses and the heterogeneity of patients, these preliminary results are encouraging. After talks with experts, GenSight Biologics has designed its ongoing Phase III trials to target a more homogeneous patient population, very recently diagnosed (less than 12 months), which could maximize the benefits and efficacy of treatment.

... that have enabled the launch of the Phase III trials in Europe and the US at the end of 2015

GenSight Biologics initiated two Phase III trials in late 2015 simultaneously in Europe and the US, to demonstrate the efficacy of GS010 in LHON patients who have suffered a loss of visual acuity with an onset of less than a year.

The main objective of these studies, named "RESCUE" and "REVERSE", is to assess the efficacy of GS010 in the treated eye versus the untreated eye, by measuring the change in visual acuity at 48 weeks compared to the visual acuity at baseline.

The 36 patients in each study will be randomized in 7 specialized investigation centers (one in France, one in Germany, one in Italy, one in the UK and 3 in the United States).

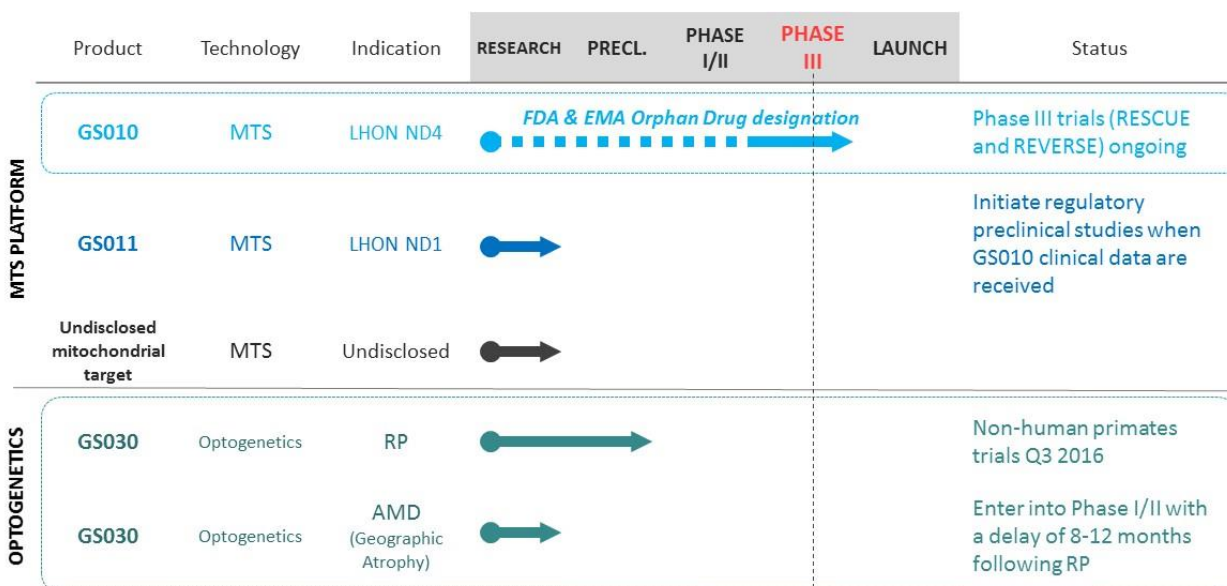
GS030: optogenetics for the treatment of retinitis pigmentosa and advanced forms of age related macular degeneration

Photoreceptor degeneration can be of genetic origin – in retinitis pigmentosa (RP) – or be linked to aging – in late forms of macular degeneration – but inevitably leads to blindness. Optogenetics uses gene

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therapy to transform other cells of the retina into photoreceptor cells aiming to restore vision in all patients, regardless of the origin of the disease. GenSight Biologics believes that its GS030 product candidate would benefit patients in the early stages of RP.

A Phase I / II clinical trial for GS030 for the treatment of all forms of retinitis pigmentosa is expected to be initiated during the second half of 2017, subject to the requirements of regulatory agencies. In addition to confirming GS030's tolerability profile, the trial will yield its first pharmacodynamic results in the first half of 2018. In parallel, GenSight Biologics is also developing GS030 for the treatment of geographic atrophies resulting from the late-stage form of age-related macular degeneration, and is expected to initiate a Phase I / II clinical trial, within 8 to 12 months following the results obtained from retinitis pigmentosa patients.



How to obtain the registration document – GenSight Biologics' registration document is available upon request and free of charge from GenSight Biologics (74 rue du Faubourg Saint-Antoine, 75012 Paris, France), or on the company's website (www.gensight-corp.com) and the AMF's website (www.amf-france.org).

Risk factors - GenSight Biologics draws the public's attention to chapter 4 "Risk factors" of the registration document and particularly to the risk factors set out in section 4.1 "Risks relating to the Group's products, market and business".

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biotechnology company discovering and developing novel therapies for neurodegenerative retinal diseases and diseases of the central nervous system. GenSight Biologics' pipeline leverages two core technology platforms, Mitochondrial Targeting Sequence (MTS) and optogenetics, to help preserve or restore vision in patients suffering from severe degenerative retinal diseases. GenSight Biologics' lead product candidate, GS010, is in Phase III trials in Leber's Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible vision loss in teens and young adults. Using its gene therapy-based approach,

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GenSight Biologics' product candidates are designed to be administered in a single treatment to each eye by intravitreal injection in order to offer patients a sustainable functional visual recovery.

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A Prospectus is been prepared (consisting of (i) a document de base and (ii) a note d'opération including the summary of the Prospectus) and will receive visa from the AMF. This Prospectus includes a section describing certain risk factors relating to the company and the offering. This Prospectus will be available on the AMF web site (www.amf-france.org) and on the company's web site (www.gensight-biologics.com). Potential investors should review the risk factors described in the Prospectus.

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