#### Press release







# Lysogene launches its IPO on Euronext's regulated market in Paris

- Capital increase of approximately €30.0 million, which may be increased to a maximum of approximately €39.7 million if the Extension Clause and Overallotment Option are fully exercised (based on the midpoint of the indicative price range)
- Subscription undertakings totaling approximately €15.0 million given by existing shareholders, representing 50% of the gross amount of the Offering, plus a €2.0 million undertaking from a new investor
- Indicative price range of between €6.80 and €9.20 per share
- Close of the Open Price Offering in France: February 6, 2017
- Close of the Global Placement: (12pm on) February 7, 2017
- Shares eligible for PEA-PME plans and FCPI accreditation of the Company

Paris, France—January 25, 2017— Lysogene (the "Company"), a biotechnology company specializing in gene therapy targeting two rare CNS diseases, today announces the launch of its initial public offering on Euronext's regulated market in Paris.

Following the registration of its *document de base* under reference number I.17-001 on January 9, 2017, the *Autorité des marchés financiers* ("**AMF**"), the French financial markets authority, granted visa no. 17-031 dated January 24, 2017 to the prospectus for Lysogene's initial public offering.

Lysogene is a biotechnology company developing new drug candidates to treat two rare neurological diseases with devastating and fatal consequences, for which there is no disease modifying treatment currently marketed. The Company specializes in developing gene therapies and has expertise in designing and delivering therapeutic gene-transfer vectors to the central nervous system ("CNS"). Lysogene aims to become a leading player in rare pediatric CNS diseases by developing these innovative drugs capable of correcting the action of defective genes and radically improving the lives of patients.

# **Rationale for the Offering**

The foreseen transaction is intended to finance Lysogene's activities and in particular to continue the development of its drug candidates. The proceeds of the Offering will mainly finance:

- The pivotal clinical trial in Europe and the United States of LYS-SAF302 as a treatment for Sanfilippo A, consuming approximately two-thirds of the net Offering proceeds, i.e. €19.0 million.
- The Phase I/II study of LYS-GM101 as a treatment for GM1 gangliosidosis, consuming approximately one-quarter of the net Offering proceeds, i.e. €6.5 million.
- the remainder of the net Offering proceeds (one-twelfth) will finance the Company's continuing activities aside from these two R&D programs





Should the Offering be reduced to 75% of its original size (based on the low end of the Offering's Indicative Price Range), the funds raised would be devoted in priority to the clinical development of its main drug candidate in MPS IIIA, LYS-SAF302.

The Company will also consider allocating a portion of these funds in due course to expanding the portfolio of drug candidates for rare CNS diseases should the Extension Clause and Overallotment Option be fully exercised.

# Lysogene's principal strengths

# Lysogene: pioneer in gene therapies offering a technology for treating rare and fatal neurological diseases

Central nervous system diseases, are a group of neurological disorders that affect the structure or function of either the spinal cord or brain. Lysosomal storage disorders ("LSDs"), often involve the CNS. They are a group of rare—mainly pediatric—monogenic diseases, caused by a gene defect affecting the functioning of proteins, the "lysosomal enzymes", resulting in the premature death of patients. As a result of each defect, specific substrates are not broken down, and build up, triggering numerous debilitating symptoms.

CNS conditions are among the hardest to treat owing to their complexity and the limited access of drugs to the brain, because it is protected by the blood-brain barrier <sup>(1)</sup>. To achieve this, the Company decided to use a gene therapy approach with direct and single administration to the CNS, which allows therapeutic agents to be delivered past the blood-brain barrier.

Gene therapy involves the transfer of genetic material to the patient to prevent, treat or cure a disease, With LSDs, the core approach of this therapy is to introduce the functional gene for the missing enzyme into the patients' cells and tissue by means of a vector such as adeno-associated viral vectors ("AAVs").

Each cell "enhanced" with the correct gene will produce a functional enzyme used within the cell's lysosome to break down the toxic substrates. In addition, part of the enzyme is secreted outside the cell and captured by neighboring or more distant cells. This "cross-correction" phenomenon allows the therapeutic enzyme to be distributed widely within the brain tissue.

# Lysogene's approach, a direct administration to the brain, would offer maximum therapeutic benefits

- ✓ Lysogene believes its technique is currently most effective because it circumvents the issue of how to pass through the blood-brain barrier—the main obstacle diminishing the likely effectiveness of all the other techniques studied
- ✓ It chiefly targets non-replicative cells, facilitating sustained and stable transgenic expression
- ✓ This administration method allows the missing enzyme to be produced *in situ*, after which it can spread throughout the brain.
- ✓ It uses a rapid proven medical procedure:
  - o already used for this disease and others

<sup>&</sup>lt;sup>1</sup> The blood-brain barrier is a group of cells that separates blood from the brain in order to regulate its flow. The blood-brain barrier also protects the central nervous system against pathogenic agents, toxins and certain hormones in the blood.





o administering the product once and in less than three hours

Two drug candidates under development for the treatment of extremely debilitating pediatric diseases causing the premature death of patients

• Proof of concept: LYS-SAF302, the first drug candidate for treating MPS IIIA, at an advanced stage of clinical development

Mucopolysaccharidosis type III A ("MPS IIIA") or Sanfilippo syndrome A is a pediatric LSD characterized by heparin sulfamidase deficiency, which leads to a toxic build-up of heparan sulfate (primary substrate) in tissue, particularly in the CNS.

To date, no treatment for this disease has a market authorization. The Company is currently conducting the non-clinical trials requested by the regulatory authorities prior to the commencement of the pivotal clinical trials for LYS-SAF302, the drug developed by Lysogene. These are due to begin by the first quarter of 2018. The US healthcare authorities ("FDA") and the European Medicines Agency ("EMA") have granted Lysogene orphan drug status for LYS-SAF302, and the FDA has granted it the rare pediatric disease designation, which will enable specific and faster development.

• Clinical trial planned for a second drug candidate, LYS-GM101, as a therapy for GM1 gangliosidosis

GM1 gangliosidosis (or Landing disease) is a severely debilitating pediatric LSD characterized by a deficiency of the  $\beta$ -galactosidase enzyme, which leads to a build-up of toxic substrates in tissue, particularly in the CNS and causes premature death in patients

As with MPS IIIA, Lysogene is not aware of disease modifying treatment for GM1 gangliosidosis.

In February 2015, Lysogene launched a collaboration with the University of Massachusetts Medical School (UMMS) and Auburn University (AU) in the United States. The aim of the project is to conduct the preclinical trials needed to prepare for clinical trials in GM1 gangliosidosis, which are due to start by the first half of 2018.

In December 2016, the FDA granted LYS-GM101 a Rare Pediatric Disease Designation.

Aim: capitalize on a renowned expertise and know-how by replicating its innovative therapeutic approach to other rare and fatal CNS diseases

Mirroring what has been done with LYS-GM101, the Company intends to capitalize on the progress it has made with its two main programs. It aims to replicate its innovative therapeutic approach by targeting other rare and fatal CNS diseases to expand its product portfolio.

#### An experienced team backed by prominent investors

The Lysogene team is highly specialized in rare diseases with renowned scientific, clinical and regulatory expertise. Lysogene partners with patient associations, leading clinical centers, opinion leaders and experts from the scientific and academic community. It is supported by its shareholders Sofinnova Partners, BpiFrance Investissement (InnoBio), and Novo A/S. Their total participation in the Offering will amount





to €15 million (see "Subscription Undertakings" hereinafter), and they will also be represented on the Company's Board of Directors.

# **Terms of the Offering**

#### **Structure of the Offering**

The shares offered for sale will be made available via a global offering (the "Offering"), consisting of the following:

- A public offering in France in the form of an open price offering (*Offre à Prix Ouvert*) aimed primarily at retail investors (the "**OPO**"); and
  - A private placement aimed primarily at institutional investors in France and in certain other countries, (the "Global Placement").

Should demand received in connection with the OPO permit, the number of shares allotted to meet orders placed via the OPO will be at least equal to 10% of the total number of shares offered for sale via the Offering prior to any exercise of the Overallotment Option.

### **Initial size of the Offering**

3,750,000 new shares to be issued through an increase in the Company's share capital in cash by means of a public offering.

#### **Extension Clause**

Up to 15% of the number of new shares initially offered for sale, i.e. a maximum of 562,500 additional new shares (the "**Extension Clause**"). The Extension Clause may be exercised in full or in part, on one single occasion, on February 7, 2017.

#### **Overallotment Option**

Up to 15% of the number of new shares offered for sale after any exercise of the Extension Clause, i.e. a maximum of 649,875 additional new shares (the "**Overallotment Option**"). This Overallotment Option may be exercised by Gilbert Dupont on behalf of the Joint Lead Managers and Bookrunners (the "**Lead Managers and Bookrunners**") in full or in part at any time on or before March 9, 2017.

# Offering's indicative price range

Between  $\in$ 6.80 and  $\in$ 9.20 per share<sup>2</sup>. The price of the new shares offered for sale via the OPO will be identical to the price of the new shares offered via the Global Placement (the "**Offering Price**").

<sup>&</sup>lt;sup>2</sup> The Offering Price may be set outside this indicative price range. Should the top of the indicative price range be increased or the Offering Price be set above the top of the (initial or revised) indicative price range, depending on the exact circumstances, either the closing date of the OPO will be postponed or another OPO subscription period will commence such that at least two trading days elapse between the date of the press release announcing the new price range and the





## **Gross proceeds of the Offering**

Approximately €30.0 million, which may be increased to approximately €34.5 million if the Extension Clause is fully exercised, and to approximately €39.7 million if the Extension Clause and the Overallotment Option are fully exercised (assuming that the Offering Price is set at €8.00, i.e. the midpoint of the indicative price range).

### Estimated net proceeds of the issue

Approximately  $\in$ 27.1 million, which may be increased to approximately  $\in$ 31.4 million if the Extension Clause is fully exercised, and to approximately  $\in$ 36.3 million if the Extension Clause and the Overallotment Option are fully exercised (assuming that the Offering Price is set at  $\in$ 8.00, i.e. the midpoint of the indicative price range).

### **Subscription undertakings**

Several investment funds managed by Sofinnova Partners, Innobio (Bpifrance Investissement) and Novo A/S have undertaken to place subscription orders totaling €15.0 million, or approximately 50% of the gross amount of the Offering (excluding the exercise of the Extension Clause and Overallotment Option and based on the midpoint of the Offering's Indicative Price Range) and 78.4% of the gross proceeds of the Offering (should the Offering be reduced to 75% and based on the low end of the Offering's Indicative Price Range), which would lead to a Company free-float that could be limited to 7.79% (should the Offering be reduced to 75%)

In addition, Financière Arbevel, a new investor, has undertaken to place a subscription order in an aggregate amount of  $\in 2.0$  million up to a maximum price per share of  $\in 8.27$ .

The intention is to meet these orders in priority and in full. However, it is possible that they may still be reduced in accordance with the customary allocation principles (chiefly in the event that the subscriptions received in connection with the Offering vastly exceed the number of shares offered for sale).

Lock-up and standstill arrangements binding the Company, the founding shareholders, members of the Company's Board of Directors and the Company's shareholders (covering all the shares and equity instruments in issue prior to the Offer)

• Length of the standstill period: 180 days

revised closing date of the OPO. Orders placed via the OPO ahead of this press release will be maintained, unless the buyers expressly revoke their orders on or before the revised closing date of the OPO. The Offering Price will be determined by matching up the supply of shares in the Global Placement with demand from investors using the bookbuilding method in accordance with customary practice. In a departure from customary practice, please note that firm subscription undertakings given by the Company's principal core shareholders totaling  $\mathfrak{C}5$  million will not be taken into account for the purpose of setting the Offering Price.

# LYSGENE



- Length of the lock-up arrangement binding the founding shareholders, members of the Company's Board of Directors and the Company's senior managers: 365 days
- Lock-up undertakings binding the core shareholders: 180 days for 100%, 270 days for 90% and 365 days for 80% of their holding.

## Eligibility of shares for PEA-PME plans and FCPI fund status

At the date of the Prospectus, Lysogene shares are eligible both for standard PEA and for "PME-ETI" PEA equity savings plans. Furthermore, Bpifrance Financement has confirmed Lysogene's *Entreprise Innovante* (innovative business) status. As a result of this 3-year accreditation period, French innovation funds (FCPIs) will be able to invest in the Company's shares.

#### **Financial intermediaries**

Société Générale and Gilbert Dupont are acting as Joint Lead Managers and Bookrunners.



Joint Lead Manager and Bookrunner



Joint Lead Manager and Bookrunner

# LYSGENE



#### **Indicative timetable of the IPO**

January 24, 2017	AMF visa on the Prospectus
January 25, 2017	Press release announcing the Offering and Opening of the Offering
February 6, 2017	<ul> <li>Close of the OPO at 5pm (Paris time) for counter subscriptions and 8pm (Paris time) for subscriptions via the internet</li> </ul>
February 7, 2017	<ul> <li>Close of the Global Placement at 12pm (Paris time)</li> <li>Setting of the Offering Price</li> <li>Possible exercise of the Extension Clause</li> <li>Beginning of the stabilization period, where applicable</li> </ul>
February 8, 2017	• Start of trading of the shares on Euronext Paris in the form of share promises (on the "Lysogene-Promesse" trading line)
February 9, 2017	Settlement-delivery of the Offering
February 10, 2017	• Start of trading in Lysogene shares on Euronext's regulated market in Paris on the "Lysogene" trading line
March 9, 2017	<ul> <li>Last day on which the Overallotment Option may be exercised</li> <li>End of the stabilization period, where applicable</li> </ul>

### **Subscription arrangements**

Persons wishing to take part in the OPO must submit their orders via a financial intermediary authorized in France no later than 5pm (Paris time) on February 6, 2017 for counter subscriptions and 8pm (Paris time) for subscriptions via the internet.

To be admissible, orders issued for the Global Placement must be received by the Joint Lead Managers and Bookrunners by 12pm (Paris time) on February 7, 2017, unless it closes early.

### **Identification codes for Lysogene shares**

Company name: LysogeneISIN code: FR0013233475

• Ticker: LYS

• Compartment: Euronext Paris (Compartment C)

• Sector: 4573 – Biotechnology

# LYSGENE



#### **How to obtain the Prospectus**

Copies of the prospectus for the Offering and the admission of Lysogene shares to Euronext's regulated market in Paris approved by the AMF on January 24, 2017 under no. 17-031 are available free of charge upon request from Lysogene (18-20 rue Jacques Dulud, 92200 Neuilly-sur-Seine) and from the Company's (<a href="https://www.lysogene.com">www.lysogene.com</a>) and the AMF's (<a href="https://www.amf-france.org">www.lysogene.com</a>) and the AMF's (<a href="https://www.amf-france.org">www.lysogene.com</a>) and the AMF's (<a href="https://www.amf-france.org">www.amf-france.org</a>) websites.

#### **Risk factors**

Investors are advised to read carefully the risk factors presented in Chapter 4 "Risk factors" of the *document de base* and especially the factors in section 4.2 "Risks arising from the Company's business activities and products", giving special regard to the factors in section 4.2.5 "Risks related to financing the development of the Company's business activities" insofar as the Company does not yet generate any revenue, and Chapter 2 "Risks related to the Offering" of the *note d'opération*, including the risk arising from the liquidity of the Company's shares should the size of the Offer be reduced to 75%, in which case the Company's free float may stand at just 7.79% upon completion of the Offering.

# **About Lysogene**

Lysogene is a clinical-stage biotechnology company pioneering in the basic research and clinical development of gene therapies that use vectors derived from adeno-associated viruses to treat rare and fatal central nervous system disorders in children, for which, to the best of the Company's knowledge, there is currently no treatment. Since 2009, Lysogene has established a solid platform and extensive network, along with innovative products in MPS IIIA and GM1 gangliosidosis, to become a global leader in gene therapies for rare and fatal central nervous system diseases.

For more information, visit <u>www.lysogene.com</u>

#### **Contacts**

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A prospectus, consisting of (i) the document de base registered by the French Autorité des marchés financiers (the "AMF") on January 9, 2017 under no. I. 17-001 and (ii) a note d'opération (the "note d'opération") including the summary of the prospectus, will be subsequently filed with the AMF. The document de base includes a section describing certain risk factors relating to the Company. The document de base is available on the AMF website (www.amf-france.org) and on the Company's website





(www.lysogene.com) and may be obtained free of charge from the Company. Potential investors should review the risk factors described in the document de base.

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