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# GENKYOTEX ANNOUNCES 2017 FIRST-HALF FINANCIAL RESULTS

- **Operating expenses in line with company's acceleration in R&D activities and new scope**
- **Robust clinical program expected to deliver first results in 2018**

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces its financial results for the six months ended June 30, 2017 prepared in accordance with IFRS standards. 2017 first-half financial statements were subject to a limited review by the Company's statutory auditors, and the interim financial report is available on the Investors section of the Company's website (in French).

**2017 first-half financial highlights**

| In thousands of euros (€) | As at June 30, 2017[1] | As at June 30, 2016[2] |
|---|---|---|
| Research & Development expenses | (5,665) | (2,552) |
| Subsidies and Research Tax Credit | 395 | 304 |
| General & Administrative expenses | (3,640) | (535) |
| **Recurring operating loss** | **(8,910)** | **(2,783)** |
| Other operating expenses | (11,408) | - |
| **Operating loss** | **(20,318)** | **(2,783)** |
| **Net loss** | **(20,368)** | **(2,922)** |
| Net loss per share (in euros) | (0.38) | (1.77) |

Given its stage of development, the Company has not generated any revenue to date, as all of its product candidates are in the Research & Development (R&D) phase.

The recurring operating loss includes share-based payments relating to the participation warrants attributed to Genkyotex Suisse SA employees in January 2017 and converted into ordinary shares for a total of €3,963 thousand (of which €2,060 thousand included in Research & Development expenses and €1,903 thousand included in general costs). This expense does not affect the Company's cash position.

[1] The first half of 2017 includes Genkyotex's results of operationsas well as Genticel's results of operations from February 28th, 2017
[2] Financial information for the first half of 2016 only includes Genkyotex's results of operations

Other R&D expenses incurred during the first half of 2017 were primarily related to the costs associated with the launch of a Phase II clinical trial of Genkyotex's lead product candidate, GKT831, in primary biliary cholangitis (PBC) and ongoing preclinical work with GKT771, the Company's second product candidate.

Other operating expenses, which totaled €11,408 thousand in the six-month period ended June 30, 2017, related mainly to the strategic combination carried out in February 2017 (including €10,898 thousand IFRS charge with no impact on the cash position) and to the restructuring costs incurred by Genkyotex SA (formerly called Genticel SA).

As at June 30, 2017, Genkyotex had cash, cash equivalents and short-term investments of €18.1 million, versus €26.8 million at December 31, 2016 (€13.9 million for Genkyotex and €13.0 million for Genticel). This decrease was primarily due to the initiation of the Phase II trial of GKT831 in PBC and to ongoing preclinical work on GKT771. This cash position does not include the reimbursement, expected in the second half of 2017, of the Research Tax Credit for 2016 estimated by the Company at approximately €3.0 million.

**2017 first-half business update and outlook**

Genkyotex aims to develop novel treatments for a number of fibrotic diseases with critical unmet needs. During the first half of 2017, the Company's key development-related activities focused on:

- **Assessing the efficacy of GKT831 in hepatic fibrosis with a clinical trial in PBC**. On June 27, 2017, the Company initiated a Phase II clinical trial in PBC with GKT831 in Europe and North America. If successful, this trial could enable a new therapeutic approach to be considered for other fibrotic diseases. Genkyotex expects interim top-line results from this study in the first half of 2018 and full results in the second half of 2018.
- **Evaluating the efficacy of GKT831 in diabetic nephropathy, a fibrotic disease.** On June 28, 2017, Genkyotex initiated a 48-week Phase II clinical trial with GKT831 in patients with type 1 diabetes and nephropathy. This investigator initiated trial will be financed by the Juvenile Diabetes Research Foundation (JDRF Australia), with additional financial support from the Baker Institute. Patient enrollment is expected to begin during the second half of 2017.
- **Identifying new indications for GKT831.** On August 3, 2017, the Company announced that GKT831 had demonstrated its ability to efficiently target cancer associated fibroblasts (CAFs) and delay tumor growth, in a study involving multiple preclinical models. The results of this study were published in the Journal of the National Cancer Institute. Based on these study results, Cancer Research UK awarded Professor Gareth Thomas, from the University of Southampton, a discovery grant to further evaluate the optimal clinical development strategy for GKT831 in oncology.
- **Initiating a Phase I clinical trial to assess the safety profile of GKT771.** Genkyotex is currently conducting preclinical studies in order to prioritize clinical indications for this product candidate that targets a number of pathological processes, including angiogenesis, pain and inflammation. Genkyotex intends to submit a clinical trial application (CTA) at the end of 2017 to conduct a Phase I clinical trial with GKT771. If approved, results from this trial could be available in the first half of 2018.
- **Expanding the Company's NOX platform by continuing exploratory preclinical research programs** in hearing loss, central nervous system (CNS) diseases and oncology indications.

- **Continuing to execute on the partnership with the Serum Institute for Vaxiclase.**

Elias Papatheodorou, CEO of Genkyotex, said: "*The first half of 2017 was highlighted by multiple key clinical and corporate developments. The increase in operating expenses primarily reflects the acceleration in our robust Research & Development programs, as well as our scope change associated with the development of our activities as a listed company on Euronext Paris and Brussels. Based on their compelling profiles, we remain confident in the potential of our multiple drug candidates, and look forward to the first clinical results of our ongoing studies.*"

## Next financial press release:

Q3 2017 business update and cash position: October 26, 2017 (after market)

## About Genkyotex

*Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. A leader in NOX therapies, its unique therapeutic approach is based on a selective inhibition of NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration.*

*Genkyotex's platform enables the identification of orally available small-molecules that selectively inhibit specific NOX enzymes. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, GKT831, a NOX1 and NOX4 inhibitor entered a phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) in the second quarter of 2017. This product candidate may also be active in other fibrotic indications. Its second product candidate, GKT771, is a NOX1 inhibitor targeting multiple pathways in angiogenesis, pain processing, and inflammation, and should enter a phase I clinical study at the end of 2017.*

*Genkyotex also has a versatile platform well-suited to the development of various immunotherapies (Vaxiclase). A partnership covering the use of Vaxiclase as an antigen per se (GTL003) has been established with Serum Institute of India Ltd (Serum Institute), the world's largest producer of vaccine doses, for the development by Serum Institute of cellular multivalent combination vaccines against a variety of infectious diseases. This partnership could generate up to $57 million in future revenues for Genkyotex, before royalties on sales.*

***For further information, please go to*** www.genkyotex.com

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*This press release may contain forward-looking statements by the company with respect to its objectives. Such statements are based upon the current beliefs, estimates and expectations of Genkyotex's management and are subject to risks and uncertainties such as the company's ability to implement its chosen strategy, customer market trends, changes in technologies and in the company's competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. These factors as well as other risks and uncertainties may prevent the company from achieving the objectives outlined in the press release and actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include uncertainties involved in the development of Genkyotex's products, which may not succeed, or in the delivery of Genkyotex's products marketing authorizations by the relevant regulatory authorities and, in general, any factor that could affects Genkyotex's capacity to commercialize the products it develops. No guarantee is given on forward-looking statements which are subject to a number of risks, notably those described in the registration document (document de reference) registered by the French Markets Authority (the AMF) on 29 June 2017 under number R.17-048., and those linked to changes in economic conditions, the financial markets, or the markets on which Genkyotex is present. Genkyotex products are currently used for clinical trials only and are not otherwise available for distribution or sale.*

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