Transgene Presents 2018 Half-Year Results and Business Update

- ✓ **Transgene obtains $48 million in Tasly Biopharmaceuticals shares with the sale of the Greater China rights of TG1050 and TG6002**
- ✓ **Key trials of Transgene's immunotherapeutics to deliver results before the end of 2018 and over the course of 2019**
- ✓ **Strong research capabilities put Company at the forefront of innovation**
  - Oncolytic virus Invir.IO™ platform progressing well
  - An ambitious personalized therapeutic vaccine platform to be presented in the coming weeks
- ✓ **€33.0 million in cash and cash equivalents providing financial visibility until the end of September 2019**

Conference call scheduled today at 6:30 p.m. CET (in English)

Strasbourg, France, September 19, 2018, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancers and infectious diseases, announces its financial results for the six-month period ended June 30, 2018, and provides an update on its clinical and preclinical portfolio.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, commented:

"2018 is a period of intense activity for Transgene. We obtained $48 million in the form of Tasly Biopharmaceuticals shares following the sale of TG1050 and TG6002 rights in Greater China. We presented new results on our oncolytic virus Pexa-Vec at ASCO that benefitted from a positive reception. We have continued to make progress with our clinical and preclinical programs.

Looking ahead we expect to announce more comprehensive clinical results from our strategic studies before the end of 2018 and over the course of 2019.

Our research efforts are focused on our world-leading viral vector expertise applied to our two core technologies: oncolytic viruses and therapeutic vaccines. With our Invir.IO™ platform, we are designing new viruses to provide a better modulation of the tumor micro-environment. We are also about to present our ambitious approach in neoantigen-based therapeutic vaccines at a scientific congress in the coming weeks.

The progress that we have made in 2018 further confirms Transgene's strategic position as leading innovator in the fight against cancer."

Clinical Pipeline Review

1. Update on company-sponsored strategic trials

Transgene has been making significant progress with its key clinical trials, which are aimed at generating proof-of-concept clinical data. Positive results from these trials would create significant partnering opportunities.

TG4010
+ Opdivo® (ICI) (nivolumab)
+chemotherapy
Phase 2

Non-small cell lung cancer (NSCLC) – 1st line
Trial of TG4010 in combination with nivolumab and with chemotherapy in patients whose tumor cells express low or undetectable levels of PD-L1.
- ✓ Collaboration deal signed with Bristol-Myers Squibb, for the supply of nivolumab.
- ✓ Centers open in Europe and the US.
- ✓ **First patient treated in January 2018**. Recruitment is progressing with the opening of additional centers; **expected completion in 2Q 2019**.
- ➲ **Evaluation of the primary endpoint (ORR) on all patients (n=35) expected in 2H 2019**.

Pexa-Vec
+ sorafenib (PHOCUS)
Phase 3

Advanced liver cancer (hepatocellular carcinoma - HCC) – 1st line
- ✓ Clinical trial being conducted by Transgene's partner, SillaJen, Inc. (sponsor).
- ✓ Ongoing global recruitment. **First patient treated in China (September 2018).**
- ➲ **First data readout expected in 2019.**

Pexa-Vec
+ Opdivo® (ICI) (nivolumab)
Phase 1/2

Advanced liver cancer (hepatocellular carcinoma - HCC) – 1st line
- ✓ Several active trial sites in France and Italy.
- ➲ **Safety review committee expected before year-end 2018.**
- ➲ **Interim analysis on 15 patients expected mid-2019 (primary endpoint: ORR).**

TG4001
+ Bavencio® (ICI) (avelumab)
Phase 1/2

HPV-positive cancers including oropharyngeal head and neck cancer – 2nd line
- ✓ Clinical collaboration agreement with Merck KGaA and Pfizer, for the supply of avelumab for the trial.
- ✓ Principal investigator: Prof. Christophe Le Tourneau (Institut Curie, Paris).
- ✓ **Following positive safety evaluation of the combination regimen, Phase 2 part is ongoing and additional sites are being activated in Europe.**
- ➲ **Phase 1 part results in 4Q 2018 (n=9 patients).**
- ➲ **Next clinical readout expected in 2H 2019.**

TG6002
Phase 1/2a

Gastro-intestinal adenocarcinoma (colon cancer)
- ✓ TG6002 is an oncolytic virus that produces chemotherapy (5-FU) in the tumor.
- ✓ Principal investigator: Prof. Philippe Cassier, Centre Léon Bérard, Lyon (France).
- ✓ Multi-center trial; INDs granted in Belgium, France and Spain.
- ➲ **First patient to be treated in the coming weeks.**

TG1050
+ Standard of care
Phase 1

Chronic hepatitis B
- ✓ Trial completed.
- ➲ **Full results to be presented at a major liver conference in 4Q 2018.**

2. Update on investigator-sponsored trials evaluating Transgene's products

Transgene is collaborating with leading physicians at world-renowned clinical centers to identify and evaluate novel treatment regimens based on the initiative of the clinicians. These trials are designed to generate further clinical data demonstrating the value of Transgene's products in exploratory clinical settings. These trials also contribute to strengthening the data packages and increase the visibility of the products amongst the medical community.

TG4010
+ Opdivo® (ICI)
(nivolumab)
Phase 2

Non-small cell lung cancer (NSCLC) – 2nd line

Trial of TG4010 in combination with nivolumab (supplied by Bristol-Myers Squibb) in a collaborative agreement with UC Davis Medical Center (USA); principal investigator: Dr. Karen Kelly; sponsor: UC Davis.

- ✓ **The prevailing use of ICIs in first-line therapy in the USA has led to a very significant slowdown in the recruitment of this trial, as patients previously treated with ICIs are excluded per protocol.**
- ✓ **Based on Dr. Kelly's recommendation, the trial will be discontinued due to poor patient accrual.**
- ✓ **No unexpected safety issues have been observed.**

Pexa-Vec
Neo-adjuvant

Solid tumors

- ✓ Principal investigator: Prof. Alan Anthoney; sponsor: University of Leeds (UK).
- ✓ Completion of the recruitment (9 patients).
- ✓ **First positive results presented at the ASCO conference in June 2018**, confirming strong anti-tumor immunity after intravenous administration. Of the four evaluable patients with liver metastases, one showed complete tumor pathological response at the time of surgery.
- ✓ **The final data from this trial will be published in an upcoming paper and will be presented at a future scientific conference.**
- ✓ **Data support ongoing development of Transgene's *Vaccinia* virus-based oncolytics.**

Pexa-Vec
+ Yervoy® (ICI)
(ipilimumab)
Phase 1

Solid tumors (ISI-JX)

- ✓ Coordinating investigator: Dr. Aurélien Marabelle; sponsor: Centre Léon Bérard, Lyon.
- ✓ **The combination regimen was well tolerated to-date.**
- ✓ **Additional sites are being activated.**

Pexa-Vec
+ metronomic cyclophosphamide
Phase 1/2a

HER2 negative breast cancer and soft tissue sarcoma (METROmaJX)

- ✓ Principal investigator: Prof. Antoine Italiano (Institut Bergonié, Bordeaux); sponsor: INCa (French national cancer institute).
- ✓ **The combination regimen was well tolerated.**
- ✓ **At the interim analysis of the patients treated for soft tissue sarcoma, the pre-specified primary endpoint was not reached; enrolment for this indication has been discontinued.**

TG6002
Phase 1/2a

Glioblastoma

- ✓ Principal investigator: Prof. Ahmed Idbahi (AP-HP, Paris), with the support of INCa; sponsor: AP-HP.
- ✓ Single-center trial.
- ✓ **No safety issues have been observed to-date.**

Sale of the Rights of TG1050 and TG6002 in Greater China

On July 10, 2018, Transgene entered into a set of agreements with Tasly Biopharmaceuticals Co., Ltd. under which Transgene sold both the T101 Greater China patent rights and its entire 50% stake in the Transgene Tasly (Tianjin) BioPharmaceuticals Co. Ltd. joint venture which already owned the T601 Greater China patent rights. Following these agreements, Tasly Biopharmaceuticals now holds all rights to research, development and commercialization for T601 and T101 in Greater China.
In return, **Transgene received a total of 27.4 million new Tasly Biopharmaceuticals shares valued at $48 million** based on the subscription price in pre-IPO financing round of Tasly Biopharmaceuticals, which took place concurrently with the transaction with Transgene. Transgene's stake represents 2.53% of Tasly Biopharmaceutical's expanded share capital. Tasly Biopharmaceuticals has announced its intention to list its shares on the Hong Kong Stock Exchange.
The transactions were finalized in August 2018.

NB: T601 and T101 are products developed in China and respectively incorporating Transgene's TG6002 and TG1050 patented technologies.

Research and preclinical portfolio

In the first half of 2018, Transgene significantly reinforced its preclinical capabilities, capitalizing on its leading viral vectors expertise in the most attractive fields of onco-immunotherapy.

- With Invir.IO™, Transgene is making progress in the increasingly attractive field of novel oncolytic viruses (OVs). The Invir.IO™ platform aims at generating multifunctional novel oncolytic viruses that incorporate several transgenes encoding for a range of specific anticancer weapons and that are capable of better modulating the tumor micro-environment.
  The Company is currently evaluating several preclinical Invir.IO™ OV candidates to identify the most attractive one to progress into clinical development. Current candidates include OVs encoding an anti-CTLA-4 antibody in a collaboration with BioInvent, as well as other anti-cancer agents (ligands, cytokines, chemokines, enzymes, etc.). **Transgene is on track to initiate the first clinical trial with the first Invir.IO™ designed virotherapy in 2019.**

- Transgene will shortly be presenting an ambitious personalized immunotherapy approach that will allow the Company to enter the promising field of personalized medicine. This approach combines **the Company's expertise in therapeutic vaccines with neoantigen vectorization and artificial intelligence.**

Transgene will provide further updates on preclinical activities in the coming months, including at key upcoming immunotherapy congresses.

Key Financials

Key elements of the income statement

(in thousands of euros)	**June 30, 2018**	**June 30, 2017**
Operating revenues	**3,548**	**3,898**
Research and development expenses	(13,767)	(16,855)
General and administrative expenses	(2,963)	(3,066)
Other expenses	(82)	(107)
Operating expenses	**(16,812)**	**(20,028)**
Operating income / (loss)	**(13,264)**	**(16,130)**
Net income / (loss)	**(14,874)**	**(18,346)**

Operating revenues amounted to €3.6 million for the first six months of 2018 compared to €3.9 million for the same period in 2017.

- Revenues from collaboration and licensing agreements amounted to €0.6 million for the first six months of 2018 versus €0.5 million in the same period in 2017.
- The research tax credit amounted to €2.8 million for the first half of 2018, compared to €3.0 million for the first half of 2017.

Research and Development (R&D) expenses amounted to €13.8 million in the first half of 2018 compared to €16.9 million for the same period in 2017. This decrease was mainly due to the 2017 milestone payment of €3.8 million ($4 million) to SillaJen, Inc. triggered by the first patient being recruited in Europe in the Phase 3 trial of Pexa-Vec (Phocus trial). External expenses for clinical projects increased by €0.5 million to €3.7 million as we continued to progress the development of all our products.

General and administrative expenses were stable at €3.0 million for the first half of 2018 compared to €3.1 million for the same period in 2017.

Net loss amounted to €14.9 million for the first half of 2018 compared to €18.3 million for the same period in 2017.

As of June 30, 2018, the Company's **cash, cash equivalents, available-for-sale financial assets and other financial assets** amounted to €33.1 million versus €41.4 million as of December 31, 2017.
Transgene's cash burn amounted to €8.4 million in the first half of 2018, compared with €12.3 million for the same period in 2017 (mainly due to the milestone payment of €3.8 million ($4 million) to SillaJen, Inc. in 2017).
Transgene confirms its **net cash burn target of approximately €25 million for 2018.**

"Our results for the first six months of 2018 are in line with our expectations. We confirm our financial visibility for the next 12 months, excluding the monetization of the Tasly Biopharmaceuticals shares," commented Jean-Philippe Del, Chief Financial Officer of Transgene.

The Board of Directors of Transgene met on September 19, 2018 and adopted the financial statements for the six-month period ended June 30, 2018. The Statutory Auditors have conducted a limited review of the interim consolidated financial statements. The half-year financial report is available on Transgene's website, https://www.transgene.fr.

A conference call in English is scheduled today, on September 19th at 6:30 p.m. CET.

Webcast link to English language conference call:
https://channel.royalcast.com/webcast/transgene/20180919_1/

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Confirmation code: 39351470#

A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.

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Notes to editors

Transgene (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's lead clinical-stage programs are: TG4010, a therapeutic vaccine against non-small cell lung cancer, Pexa-Vec, an oncolytic virus against liver cancer, and TG4001, a therapeutic vaccine against HPV-positive head and neck cancers. The Company has several other programs in clinical development, including TG1050 (chronic hepatitis B) and TG6002 (solid tumors).

With its proprietary Invir.IO™, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses.

Additional information about Transgene is available at www.transgene.fr.

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Disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. There can be no guarantee that (i) the results of pre-clinical work and prior clinical trials will be predictive of the results of the clinical trials currently underway, (ii) regulatory authorities will agree with the Company's further development plans for its therapies, or (iii) the Company will find development and commercialization partners for its therapies in a timely manner and on satisfactory terms and conditions, if at all. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development.

For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risques") section of the Document de Référence, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

Appendices

Consolidated balance sheet, IFRS

(in € thousands)

ASSETS	June 30, 2018	Dec. 31, 2017
Current assets:		
Cash and cash equivalents	4,403	1,643
Other current financial assets	28,641	39,762
Cash, cash equivalents and other current financial assets:	**33,044**	**41,405**
Trade receivables	1,813	2,564
Inventories	314	270
Other current assets	13,728	14,497
Assets available for sale	2,412	-
Total current assets	**51,311**	**58,736**
Non-current assets:		
Property, plant and equipment	13,921	13,604
Intangible assets	205	250
Non-current financial assets	4,078	3,971
Investments in associates	-	2,916
Other non-current assets	15,611	21,396
Total non-current assets	**33,815**	**42,137**
Total assets	**85,126**	**100,873**

LIABILITIES AND EQUITY	June 30, 2018	Dec. 31, 2017
Current liabilities:		
Trade payables	3,745	2,868
Current financial liabilities	11,145	10,283
Provisions for risks	18	356
Other current liabilities	3,662	3,359
Total current liabilities	**18,570**	**16,866**
Non-current liabilities:		
Non-current financial liabilities	48,727	51,717
Employee benefits	3,864	3,710
Other non-current liabilities	324	**491**
Total non-current liabilities	**52,915**	**55,918**
Total liabilities	**71,485**	**72,784**
Equity:		
Share capital	62,276	62,075
Share premiums et reserves	512,410	512,228
Retained Earnings	(545,468)	(513,194)
Profit/(loss) for the period	(14,874)	(32,274)
Other comprehensive income/(loss)	(703)	(746)
Total equity attributable to Company shareholders	**13,641**	**28,089**
Total equity and liabilities	**85,126**	**100,873**

Consolidated income statement, IFRS
(in € thousands, except for per-share data)

	June 30, 2018	June 30, 2017
Revenue from collaborative and licensing agreements	605	472
Public funding for research expenses	2,837	3,028
Other income	106	398
Operating income	**3,548**	**3,898**
Research and development expenses	(13,767)	(16,855)
General and administrative expenses	(2,963)	(3,066)
Other expenses	(82)	(107)
Operating expenses	**(16,812)**	**(20,028)**
Operating income/(loss)	**(13,264)**	**(16,130)**
Net finance cost	(1,107)	(981)
Share of profit/(loss) of associates	(503)	(1,235)
Income tax expense	**(14,874)**	**(18,346)**
Income tax expense	-	-
Comprehensive net income/(loss)	**(14,874)**	**(18,346)**
Basic loss per share (€)	(0.24)	(0.33)
Diluted earnings per share (€)	(0.24)	(0.33)

Cash Flow statement, IFRS
(in € thousands)

	June 30, 2018	June 30, 2017
Cash flow from operating activities:		
Net income/(loss) from continuing operations	(14,874)	(18,346)
Cancellation of financial income	1,107	981
Elimination of non-cash items		
Income of associates	503	1,235
Provisions	(184)	(770)
Depreciation	866	747
Share-based payments	202	218
Other	11	18
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow:	**(12,369)**	**(15,917)**
Change in operating working capital requirements:		
Current receivables and prepaid expenses	1,046	(78)
Inventories and work in progress	(44)	27
Research tax credit (RTC)	(2,914)	(3,113)
Other current assets	289	1,119
Trade payables	996	(408)
Prepaid income	(179)	1,026
Employee benefits	79	(563)
Other current liabilities	236	(20)
Net cash used in operating activities:	**(12,860)**	**(17,927)**
Cash flows from investing activities:		
(Acquisitions)/disposals of property, plant and equipment	(1,243)	160
(Acquisitions)/disposals of intangible assets	(25)	(10)
Other (acquisitions)/disposals	891	10
Net cash used in investing activities:	**(377)**	**160**
Cash flows from financing activities:		
Net financial income/(loss) proceeds	(67)	(239)
Conditional subsidies	30	29
(Acquisition)/disposal of other financial assets	11,120	10,499
Net amounts received for financing of tax credits	4,669	6,294
Financial leases	244	(578)
Net cash generated from/(used in) financing activities:	**15,996**	**16,005**
Effect of changes in exchange rates on cash and cash equivalents	1	(2)
Net increase/(decrease) in cash and cash equivalents:	**2,760**	**(1,764)**
Cash and cash equivalents at beginning of period	1,643	4,855
Cash and cash equivalents at end of period:	**4,403**	**3,091**
Investments in other current financial assets	28,642	40,852
Cash, cash equivalents and other current financial assets:	**33,045**	**43,943**