Transgene Provides an Update on its Development Strategy and on its First Half-Year 2016 Financials

- ✓ **Programs progressing in line with strategy**
- ✓ **Significant reduction of net loss: €12.2 million compared to €28.1 million in H1 2015**
- ✓ **€33.4 million in cash and cash equivalents as of June 30, 2016**
- ✓ **Cash burn guidance confirmed around €35 million in 2016**

Conference call scheduled in English on September 6th, 2016 at 06:00 PM CET (12:00 PM EST)

Strasbourg, France, September 5, 2016, 5:35 pm CET - Transgene (Euronext Paris: TNG), a company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases, today announced its financial results for the six-month period ended June 30, 2016 and published an update on its business and on the development of its portfolio of therapeutic vaccines and oncolytic viruses.

Since the beginning of the year, Transgene has focused its efforts on implementing its strategy aimed at combining Transgene's immunotherapies with other immunotherapy treatment approaches, in particular immune checkpoint inhibitors (ICIs). The power of these combinations was the subject of great interest at the recent annual American Society of Clinical Oncology (ASCO) meeting that was held in Chicago in June.

The scientific rationale of these combinations is to use Transgene's immunotherapies, such as therapeutic vaccines and oncolytic viruses, to arm and stimulate a cancer-specific immune response while the ICIs further enhance their effects by blocking a pathway that acts as a brake on this immune response. Transgene has already demonstrated the positive effects of these combinations in several preclinical tumor models. More generally, these mechanisms are now widely acknowledged in the scientific community and have been reported in a growing number of publications. Combining these immunotherapies and their different mechanisms of action aims to both **improve the survival outcomes for individual patients and to increase the number of patients that will respond positively to the treatments**. Both clinicians and pharma companies have been impressed with the promising clinical results that we have generated with our products to-date. **The first readouts from these combination clinical trials, which are due to begin shortly, are expected as soon as 2017**.

In parallel with this progress in our clinical development activities, our research teams have been able to showcase **Transgene's capacity to be at the forefront of innovation** in the immunotherapy space.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene said: *"With its focus on research and development activities, Transgene has all the elements needed to position itself as an acknowledged leader in the field of immunotherapy. We are actively working to deliver the improved treatment options that patients with severe diseases clearly need, and to materialize development partnerships."*

Product pipeline review

1. Therapeutic Vaccines

TG4010: development focused on Phase 2 clinical trials in combination with ICIs

TG4010 is a therapeutic vaccine that induces an immune response against MUC1 expressing tumors, such as non-squamous non-small cell lung cancer (NSCLC). TG4010's mechanism of action and excellent safety profile make it a very suitable candidate for combinations with other therapies.

TG4010's development plan aims at positioning Transgene in all relevant settings of either first or second line treatment of NSCLC patients by the end of 2017. Transgene will focus exclusively on Phase 2 studies that can generate a comprehensive data package as early as 2017. The Company has decided that the Phase 3 study of TG4010 in combination with chemotherapy in first line treatment will not be launched, in order to focus initially on "PD-L1 negative[1]" patients.

Recent clinical trials in NSCLC have shown that a number of ICIs deliver efficacy in first line treatment. However, only about 30% of patients respond to these therapies. Therefore, in first line treatment, where chemotherapy is currently the standard of care, there still remains a significant need for improved therapeutic options, notably for "PD-L1 negative" patients. In second line treatment where ICIs have been approved, there also remains a significant need to improve the prognosis and to increase the number of patients that respond to treatments. Transgene's products could be instrumental in achieving these goals.

In line with its strategy, Transgene intends to capitalize on the recent developments in lung cancer treatment to make TG4010 the ideal candidate for combination regimens with current and future standards of care.

TG4010 **+ Opdivo®** (nivolumab) Phase 2	*Non-small cell lung cancer (NSCLC) – 2nd line* ✓ Trial expected to start in H2 2016 (NCT02823990) and first readout expected in 2017 ✓ Trial of TG4010 in combination with Opdivo®, conducted by UC Davis Medical Center (USA)
TG4010 **+ ICI** Phase 2	*Non-small cell lung cancer (NSCLC) – 1st line* ✓ Preparation for Phase 2 clinical trials (in patients expressing low or undetectable levels of PD-L1) ✓ Trials expected to start in H1 2017

[1] A molecule called PD-1 can be found at the surface of T cells. It binds with another molecule, PD-L1 that can be found on the surface of certain cancer cells. This interaction prevents T cells from attacking the abnormal cell, and allows the development of the tumor. By inhibiting PD-1 or PD-L1, ICIs help the immune system to eliminate cancer cells again. Nevertheless, these markers can be expressed at different levels in cancer patients. ICIs have demonstrated a significant efficacy in "high PD-L1" patients. ICIs have to date not been able to demonstrate a sufficient efficacy in patients with low or undetectable levels of PD-L1 ("PD-L1 negative" patients).

TG4001: preparation of a Phase 2 clinical trial in combination with ICI

TG4001 is a therapeutic vaccine that has already been administered to more than 300 patients with high grade cervical intra-epithelial neoplasia (CIN 2/3). It has demonstrated good safety, a significant HPV clearance rate and promising efficacy results. Its mechanism of action and good safety profile make TG4001 an appropriate candidate for combinations with other therapies, such as ICIs.

TG4001 + ICI Phase 2	*HPV positive head and neck cancer – 2nd line* ✓ Trial expected to start in H1 2017 ✓ Prof. Christophe Le Tourneau, Institut Curie, principal investigator ✓ Transgene will be the sponsor of the trial

TG1050: ongoing Phase 1/1b trial

TG1050 is a therapeutic vaccine for the treatment of chronic hepatitis B. Transgene has initiated, in 2015, a first-in-man study (NCT02428400) evaluating the safety and tolerability of TG1050 in patients who are currently being treated for chronic HBV infection with standard-of-care antiviral therapy. TG1050 is also being developed in China, where Transgene operates a joint-venture with Tasly Biopharmaceutical Technology.

TG1050 + Standard-of-Care Antiviral Phase 1/1b	*Chronic hepatitis B* ✓ Phase 1/1b clinical trial is progressing following positive recommendation of the Safety Review Committee in July 2016 ✓ IND number granted in China ✓ First data readout in H2 2017

2. Oncolytic viruses

Pexa-Vec: launch of the Phase 3 trial, preparation of the Phase 2 clinical trials in combination with ICIs

Pexa-Vec is an oncolytic virus designed to selectively destroy cancer cells through the lysis (breakdown) of cancer cells through viral replication, the reduction of the blood supply to tumors through vascular disruption, and the stimulation of the body's immune response against cancer cells. Its mechanism of action and its safety profile make it an appropriate candidate for combinations in solid tumors.

Pexa-Vec + sorafenib (PHOCUS) Phase 3	*Advanced liver cancer (hepatocellular carcinoma - HCC) – 1st line* ✓ 1st patient included and opening of clinical centers is progressing ✓ Poster presentation at ASCO annual meeting ✓ Clinical trial conducted by SillaJen, Inc., Transgene's partner ✓ First data readout expected in 2019
Pexa-Vec + ipilimumab Phase 2	*Solid tumors* ✓ Preparation of Phase 2 clinical trial with Centre Léon Bérard, the sponsor of the trial ✓ Trial expected to start in H2 2016 and first readouts in 2017
Pexa-Vec + nivolumab Phase 2	*Advanced liver cancer (hepatocellular carcinoma - HCC) – 1st line* ✓ Preparation of Phase 2 clinical trial (USA + Europe) ✓ Trial expected to start in H1 2017

TG6002: preparation of first-in-human trial

TG6002 is the next generation of oncolytic immunotherapy. It has been designed to induce the breakdown of cancer cells (oncolysis) and express the FCU1 gene in cancer cells it has infected. The expression of this gene causes these cancer cells to transform the non-cytotoxic pro-drug, flucytosine (5-FC), into 5-FU, a widely used chemotherapy. Because this mechanism of action is different from standard therapies, TG6002 could potentially be used both in combination or as a monotherapy once a cancer becomes resistant to standard therapy.

TG6002 Phase 1	*Glioblastoma* ✓ Preparation of a Phase 1 clinical trial with AP-HP (Pr Delattre principal investigator), with the support of INCA (French national cancer institute) ✓ Trial expected to start in H1 2017

3. Preclinical portfolio

During the first six months of 2016, Transgene has focused its preclinical research on two key topics:

- The design of new, highly innovative oncolytic viruses with embedded payloads such as ICIs, or enzymes, either prodrug-activating enzymes or enzymes that can degrade immunosuppressive compounds. These novel viruses are expected to modulate the tumor microenvironment and to improve the potency of the anti-tumor immune response;
- The development of innovative modalities for the preclinical screening, of new mode of administration, and the further characterization of our new candidate products.

Several posters have been presented at key conferences, which allowed the Company to introduce its most recent results in the fields of onco-immunology and chronic infectious diseases. For example, at the last AACR (American Association for Cancer Research) meeting, Transgene presented a poster reporting the features of an oncolytic vaccinia virus expressing an anti-PD-1 antibody, thus demonstrating our capacity to engineer advanced multifunctional viruses in a so called “2 in 1” approach.

Transgene expects that the integration of advanced therapeutic payloads within an oncolytic virus will allow it to generate several new drug candidates.

Corporate

- Restructuring plan and sale of the production asset to ABL Europe for €3.5 million finalized. Annualized savings are estimated to be approximately €15 million.
- Management team strengthened: Maud Brandely, MD, PhD appointed Chief Medical Officer, and John Felitti, JD, LLM appointed General Counsel & Corporate Secretary

Key financials

Key elements of the income statement

(in thousands of euros)	**June 30, 2016**	**June 30, 2015**
Operating revenues	**4,875**	**5,255**
Research and development expenses	(12,504)	(16,907)
General and administrative expenses	(3,406)	(2,991)
Other revenue and (expenses), net	336	(5,536)
Net operating expenses	**(15,574)**	**(25,434)**
Operating income / (loss) from continuing operations	**(10,699)**	**(20,179)**
Net income / (loss) from continuing operations	**(11,639)**	**(21,659)**
Net income / (loss) from discontinued operations	***(514)***	***(6,424)***
Net income	**(12,153)**	**(28,083)**

Operating revenues amounted to €4.9 million in the six months to June 30, 2016 against €5.3 million in the corresponding period in 2015. Revenues from collaboration and licensing agreements amounted to €1.9 million versus €0.8 million in the same period last year. Theses revenues come mainly from fees for conducting research and development activities for third parties and from royalties on licensed products. A one-off revenue of €1.3 million came from Sanofi Chimie.
Government financing of research expenditure amounted to €3.0 million and €4.5 million for the first six months of 2016 and 2015 respectively. These figures include a research credit tax of €2.9 million for the six-month period to June 30, 2016, compared to €4.3 million in the same period in 2015. This reduction was due to the lower level of research expenditure that was eligible for the research tax credit. This was as a result of the restructuring of the company which was announced in the first half of 2015.

Research and development expenses (R&D) amounted to €12.6 million for the first half of 2016 compared to €16.9 million for the same period in 2015. This decline was mainly due to the reorganization of the company that resulted from a decision made in June 2015. The increase in external expenses for clinical trials reflected the execution of the development plans for TG4010, Pexa-Vec and TG1050. General and administrative expenses stood at €3.4 million for the first six months of 2016 compared to €3.0 million during the same period in 2015.

The **overall net loss** was €12.2 million for the first half of 2016 a significant reduction compared to the €28.1 million net loss in the first half of 2015.

As of June 30, 2016, the Company had **cash, cash equivalents, available-for-sale financial assets and other financial assets** of €33.4 million. This compares to €31.7 million as of December 31, 2015.

- Cash burn (excluding EIB financing) for the first six months of 2016 fell by 37% to €8.2 million, compared to €13.0 million in the same period in 2015. Net cash outflows linked to the restructuring plan amounted to €3.6 million in the first half of 2016. Excluding the cash-out related to the restructuring plan, cash burn was €4.6 million.
- In June 2016, Transgene drew the first tranche of the EIB (European Investment Bank) loan facility secured in January 2016. This €10 million tranche will be repayable in 2021, and the accrued interest will be payable from 2019. The overall size of the EIB loan facility is €20 million.

"The results of the first six months of 2016 reflect the completion of the reorganization started in 2015. We have significantly reduced our operational costs, which allows us to fund our promising preclinical and clinical developments, while containing our cash consumption", commented Jean-Philippe Del, Chief Financial Officer of Transgene.

Transgene confirms that it expects its cash burn to be around €35 million in 2016. This forecast includes a significant increase in cash consumption that is expected in the second half of 2016 due to:

- An acceleration of our clinical development plan, and the related expenses;
- Exceptional cash payments including:
  - A milestone payment to SillaJen, Inc., when the first patient is recruited in Europe in the Phase 3 trial of Pexa-Vec (PHOCUS trial),
  - A capital increase of our joint-venture in China with Tasly Biopharmaceutical Technology;
- Major cash-ins in the first half of 2016 included tax credit financing (€7.6 million) and a one-off payment from Sanofi Chimie (€1.3 million).

As a reminder, the Company still benefits from access to further funding that can be activated in 2016: namely the second tranche of the EIB loan (€10 million) and the commitment given by Institut Mérieux for up to €10 million.

The Board of Directors of Transgene met on September 1, 2016 and reviewed the financial statements for the six-month period ended June 30, 2016. The Statutory Auditors have conducted a review of the interim consolidated financial statements. The half-year financial report is available on Transgene's website, www.transgene.com.

Conference call (in French) scheduled on: September 5th at 06:00 pm CET (12:00 pm EST) ***Webcast link to French language conference call:*** http://edge.media-server.com/m/p/bpgh4mbi ***Participant telephone numbers:*** France: +33 (0)1 76 77 22 25 UK: +44 (0)20 3427 1912 USA: + 1 212 444 0481 Confirmation code: **7860102** ***Mobile access:*** A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.	**Conférence téléphonique (anglais) :** September 6th at 06:00 pm CET (12:00 pm EST) ***Webcast link to English language conference call:*** http://edge.media-server.com/m/p/oermaiem ***Participant telephone numbers:*** France: +33 (0)1 76 77 22 30 UK: +44 (0)20 3427 1916 USA: +1 212 444 0895 Confirmation code: **5713370** ***Mobile access:*** A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.

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About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical 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 two lead clinical-stage programs are: TG4010, a therapeutic vaccine for non-small cell lung cancer and Pexa-Vec, an oncolytic virus for liver cancer. The Company has several other programs in clinical and pre-clinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as a joint venture in China. 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. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. 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 Risque") 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, 2016	December 31, 2015
Current assets:		
Cash and cash equivalents	5,608	3,285
Other current financial assets	27,760	28,365
Cash, cash equivalents and other current financial assets:	**33,368**	**31,650**
Trade receivables	2,384	1,784
Inventories	151	1,164
Other current assets	15,324	12,930
Assets available for sale	-	3,500
Total current assets	**51,227**	**51,028**
Non-current assets:		
Property, plant and equipment	15,357	16,559
Intangible assets	512	485
Financial fixed assets	5,064	4,050
Investments in associates	734	1,148
Other non-current assets	21,623	27,599
Total non-current assets	**43,290**	**49,841**
Total assets	**94,517**	**100,869**

LIABILITIES AND EQUITY	June 30, 2016	December 31, 2015
Current liabilities:		
Trade payables	6,985	6,521
Financial liabilities	9,967	9,396
Provisions for risks	3,249	7,038
Other current liabilities	3,356	3,770
Total current liabilities	**23,557**	**26,725**
Non-current liabilities:		
Financial liabilities	53,169	44,401
Employee benefits	3,335	3,196
Other non-current liabilities	-	-
Total non-current liabilities	**56,504**	**47,597**
Total liabilities	**80,061**	**74,322**
Equity:		
Share capital	38,545	88,196
Share premiums and reserves	476,875	476,788
Retained Earnings	(487,987)	(491,263)
Profit (loss) for the period	(12,153)	(46,374)
Other comprehensive income	(824)	(800)
Total equity attributable to Company shareholders	**14,456**	**26,547**
Total equity and liabilities	**94,517**	**100,869**

CONSOLIDATED INCOME STATEMENT, IFRS

(In € thousands, except for per-share data)

	June 30, 2016	June 30, 2015
Revenue from collaborative and licensing agreements	1,905	777
Government financing for research expenditure	2,970	4,478
Operating income	**4,875**	**5,255**
Research and development expenses	(12,504)	(16,907)
General and administrative expenses	(3,406)	(2,991)
Other income and (expenses), net	336	(5,536)
Net operating expenses	**(15,574)**	**(25,434)**
Operating income from continuing operations	**(10,699)**	**(20,179)**
Finance cost	(526)	(882)
Share of profit (loss) of associates	(414)	(598)
Income (loss) before tax	**(11,639)**	**(21,659)**
Income tax expense	-	-
Net income/(loss) from continuing operations	**(11,639)**	**(21,659)**
Net income/(loss) from discontinued operations	**(514)**	**(6,424)**
Net income	**(12,153)**	**(28,083)**
Basic loss per share (€)	(0.32)	(0.73)
Diluted earnings per share (€)	(0.32)	(0.73)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME, IFRS

(In € thousands)

	June 30, 2016	June 30, 2015
Net income	**(12,153)**	**(28,083)**
Foreign exchange gains/(losses)	(2)	13
Revaluation of hedging instruments	(22)	102
Other comprehensive income re-classifiable into profit or loss	**(24)**	**115**
Net comprehensive income	**(12,177)**	**(27,968)**
Of which, equity holder of the parent:	**(12,177)**	**(27,968)**
Of which, minority interests:	-	-

CASH FLOW STATEMENT, IFRS
(in € thousands)

	June 30, 2016	June 30, 2015
Cash flow from operating activities:		
Net income/(loss) from continuing operations	(11,638)	(28,083)
Net income/(loss) from discontinued operations	(514)	-
Cancellation of financial income	526	882
Elimination of non-cash items		
Income of associates	414	598
Provisions	(6,593)	8,933
Depreciation	1,291	1,489
Share-based payments	87	231
Others	6,220	6
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow:	**(10,207)**	**(15,944)**
Change in operating working capital requirements:		
Current receivables and prepaid expenses	(2,186)	(202)
Inventories and work in progress	1,013	12
Research tax credit	(2,997)	(4,487)
Assets available for sale	2,000	-
Other current assets	(2,347)	311
Trade payables	414	(169)
Prepaid income	(65)	376
Employee benefits	(348)	293
Other current liabilities	(2)	(2)
Net cash used in operating activities:	**(14,725)**	**(19,812)**
Cash flows from investing activities:		
(Acquisitions)/disposals of property, plant and equipment	159	(578)
(Acquisitions)/disposals of intangible assets	(4)	(4)
Other (acquisitions)/disposals	330	355
Net cash used in investing activities:	**485**	**(227)**
Cash flow from financing activities:		
Net financial income proceeds	(130)	(443)
Gross proceeds from the issuance of shares	-	111
Share issue costs	-	-
Conditional subsidies	-	-
(Acquisition)/disposal of other financial assets	605	13,246
Net tax credit financing	6,760	7,975
Bank loan	10,000	-
Financial leases	(670)	(543)
Net cash generated from/(used in) financing activities:	**16,566**	**20,346**
Effect of changes in exchange rates on cash and cash equivalents	(2)	13
Net increase/(decrease) in cash and cash equivalents:	**2,324**	**320**
Cash and cash equivalents at beginning of period	3,285	3,513
Cash and cash equivalents at end of period:	**5,609**	**3,833**
Investments in other current financial assets	27,760	49,175
Cash, cash equivalents and other current financial assets:	**33,369**	**53,008**