

# First half-year 2017 in line with our objectives: All clinical programs progressing and new collaboration agreements signed

#### ✓ Seven active clinical trials:

- First patients treated in four combination trials assessing TG4010 (lung cancer) or Pexa-Vec (liver cancer and other solid tumors)
- ✓ Two collaboration agreements signed with:
  - Bristol-Myers Squibb, for a combination clinical trial of TG4010 (1<sup>st</sup>-line treatment of lung cancer)
  - Servier, for a scientific collaboration to improve the production process for allogenic CAR-T cells
- ✓ Cash and cash equivalents as of June 30, 2017: €43.9 million, financial visibility confirmed to the end of 2018

**Strasbourg, France, September 13, 2017, 5:35 p.m. CET** – Transgene (Euronext Paris: TNG), a biotechnology company focused on designing and developing viral-based immune-targeted therapies, today announced its financial results for the six-month period ended June 30, 2017, and reviews the progress of it products portfolio since the beginning of the year.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene said: "*Transgene is continuing to successfully execute its strategy. We are making progress with our clinical development plans with seven active trials as of today, and in parallel we are continuing to advance our cutting edge research program.* 

Four of the clinical trials are aiming to confirm the potential of TG4010 or Pexa-Vec in combination with immune checkpoint inhibitors (ICIs), including in two high unmet need indications, lung and liver cancer.

We have signed two collaborations, one with Bristol-Myers Squibb (BMS) covering a combination study with TG4010 in the first-line treatment of lung cancer, and one with Servier for the design of an optimized production process of allogenic CAR-T cells using our viral vectorization technology. These new deals build on our existing collaborations with BMS for TG4010 in the 2<sup>nd</sup>-line treatment of lung cancer and with Merck KGaA/Pfizer for TG4001 in head and neck cancers. We believe these agreements provide strong validation of the potential of our immunotherapy approach.

With our current funding, Transgene is well placed to progress its programs through to the end of 2018. We will continue to focus all of our energy to advance our multiple clinical trials and to seize the development opportunities that they could create for Transgene."

### **1. Therapeutic Vaccines**

#### TG4010: combination trial with nivolumab (ICI); collaborations with Bristol-Myers Squibb

TG4010 is a therapeutic vaccine being developed in advanced-stage non-squamous non-small cell lung cancer (NSCLC). TG4010's mechanism of action, excellent safety profile and existing clinical data make it a very suitable candidate for combinations with other therapies.

The clinical trials aim to confirm the synergies that are expected to result from the combination of a therapeutic vaccine and an ICI. The expected clinical benefits of the combination are an increase in the response rate, in the quality and in the duration of the response to current and future standards of care.

TG4010	<u>Non-small cell lung cancer (NSCLC) – 1<sup>st</sup>-line</u>
+ Opdivo <sup>®</sup> (ICI)	$\checkmark$ Collaboration deal signed in April 2017 with Bristol-Myers Squibb, that will
(nivolumab)	supply nivolumab
+chemotherapy	$\checkmark$ Preparation of a Phase 2 clinical trial combining TG4010 with nivolumab and
Phase 2	with chemotherapy in patients with tumor cells expressing low or undetectable
	levels of PD-L1
	$\checkmark$ FDA IND approval granted to begin the clinical trial in the USA
	$\checkmark$ First patient expected to be enrolled at the end of 2017
TG4010	<u>Non-small cell lung cancer (NSCLC) – 2<sup>nd</sup>-line</u>
+ Opdivo <sup>®</sup> (ICI)	✓ Trial of TG4010 in combination with nivolumab, that will be provided by Bristol-
(nivolumab)	Myers Squibb, within a collaborative agreement with UC Davis Medical Center
Phase 2	(USA) – Principal investigator: Dr. Karen Kelly
	$\checkmark$ First patient treated in March 2017; the trial's 4 sites are now open
	✓ First results expected beginning of 2018

# TG4001: trial in combination with avelumab (ICI), based on a collaboration agreement with Merck KGaA and Pfizer

TG4001 is a therapeutic vaccine that has already been administered to more than 300 subjects in previous clinical trials. TG4001 has demonstrated good tolerability, 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.

TG4001	<u>HPV positive head and neck cancer – 2<sup>nd</sup>-line</u>
+ Bavencio <sup>®</sup> (ICI)	✓ Clinical collaboration agreement with Merck KGaA and Pfizer, for the supply of
(avelumab)	avelumab for the trial
Phase 1/2	$\checkmark$ Principal investigator: Prof. Christophe Le Tourneau (Institut Curie, Paris);
	multi-center trial
	✓ First patient expected to be treated shortly

#### TG1050: results expected in 2H 2017

TG1050 is a therapeutic vaccine for the treatment of chronic hepatitis B. At the end of 2015, Transgene started a study evaluating the safety and tolerability of TG1050 in patients who are currently being treated for chronic HBV infection with standard-of-care antiviral therapy. The technology of TG1050 is also being developed in China, where Transgene operates a joint-venture with Tasly Biopharmaceutical Technology.

TG1050Chronic hepatitis B+ Standard-of-<br/>Care Antiviral<br/>Phase 1/1b✓ Results from the first part of the study to be presented at AASLD (October 2017)<br/>✓ Several patents granted, extending protection to 2032

## 2. Oncolytic viruses

#### Pexa-Vec: ongoing Phase 3 trial, initiation of the Phase 2 clinical combination trials

Pexa-Vec is an oncolytic virus designed to selectively target and destroy cancer cells through intracellular viral replication (oncolysis), and by stimulating the body's immune response against cancer cells. Its mechanism of action and tolerability profile make it an appropriate candidate for use in combinations.

Pexa-Vec	<u>Advanced liver cancer (hepatocellular carcinoma - HCC) – 1<sup>st</sup>-line</u>
+ sorafenib	✓ Clinical trial being conducted by SillaJen, Inc., Transgene's partner
(PHOCUS)	✓ Ongoing recruitment. First patient treated in Europe in April 2017
Phase 3	$\checkmark$ Trial recruitment authorized in China (July 2017)
	$\checkmark$ First data readout expected in 2019
Pexa-Vec	Advanced liver cancer (hepatocellular carcinoma - HCC) – 1 <sup>st</sup> -line
+ Opdivo <sup>®</sup> (ICI)	✓ Principal investigator: Prof. Olivier Rosmorduc (Pitié Salpêtrière, Paris)
(nivolumab)	First patient treated in July 2017; several active trial sites
Phase 2	$\checkmark$ First data readout expected in 2018
Pexa-Vec	HER2 negative breast cancer et soft tissue sarcoma (METROmaJX)
+ metronomic	✓ Principal investigator: Prof. Antoine Italiano (Institut Bergonié, Bordeaux);
cyclophosphamide	Sponsor : INCa
Phase 1/2	$\checkmark$ Positive results of the Phase 1 part presented at ESMO 2017 (Sept. 2017)
	$\checkmark$ First patient of the Phase 2a part treated in April 2017
Pexa-Vec	Solid tumors (ISI-JX)
+ Yervoy <sup>®</sup> (ICI)	✓ Principal investigator: Dr. Aurélien Marabelle, MD, PhD (Centre Léon Bérard, Lyon)
(ipilimumab)	✓ First patient treated in February 2017
Phase 1	$\checkmark$ First readout expected around the end of 2017

#### TG6002: preparation of first-in-human trial

TG6002 is a next generation oncolytic immunotherapy. It has been designed to induce the breakdown of cancer cells (oncolysis) and express the FCU1 gene in the cancer cells it has infected leading to the local production of 5-FU, a widely-used chemotherapy. TG6002 could potentially be used both in combination or as monotherapy in recurrent cancers.

TG6002	<u>Glioblastoma</u>
Phase 1	✓ Principal investigator: Prof. J-Y Delattre (AP-HP, Paris), with the support of INCa
	(French national cancer institute)
	✓ First patient expected in the coming weeks

# 3. Research and preclinical portfolio

Research and preclinical highlights during the first half were:

- The **signing of a collaboration agreement with Servier** in June 2017 aimed at designing an original process for the production of allogenenic CAR-T cells which would provide better yield and a reduced number of steps. This collaboration highlights Transgene's expertise in viral vectorization;
- A poster presentation at the American Association for Cancer Research (AACR) meeting in April 2017 and the publication of preclinical data supporting the clinical development of TG6002 in *Cancer Research* in July 2017;
- The **filing of several patent applications** ensuring the protection of the innovative technologies developed by Transgene for new products (therapeutic vaccines and oncolytic viruses).

- **A R & D Day for investors** on 22 June 2017 in Paris. At this meeting, Transgene presented **its new** generation of immunotherapies based on multifunctional (armed) oncolytic viruses aimed at improving the treatment of cancer.

### Key financials

The Board of Directors of Transgene met on September 12, 2017, and reviewed the financial statements for the six-month period ended June 30, 2017. The Statutory Auditors have conducted a review of the interim consolidated financial statements. The half-year financial report is available on Transgene's website, <u>https://www.transgene.fr</u>.

#### Key elements of the income statement

(in thousands of euros)	June 30, 2017	June 30, 2016
Operating revenues	3,898	5,339
Research and development expenses	(16,855)	(12,504)
General and administrative expenses	(3,066)	(3,406)
Other revenue and (expenses), net	(107)	(128)
Operating expenses	(20,028)	(16,038)
Operating income / (loss)	(16,130)	(10,699)
Net income / (loss)	(18,346)	(11,639)
Net income / (loss) from discontinued operations	-	(514)
Comprehensive net income	(18,346)	(12,153)

Operating revenues amounted to €3.9 million for the first six months of 2017 compared to €5.3 million for the same period in 2016. Excluding the €1.3 million one-off revenue received from Sanofi Chimie in 2016, Transgene's revenues remained stable compared to the first half of 2016.

- Revenues from collaboration and licensing agreements amounted to €0.5 million for the first six months of 2017 versus €1.9 million in the same period in 2016, that included €1.3 million from Sanofi Chimie. Under the collaboration agreement with Servier signed in June 2017, Transgene invoiced an initial amount of €1.0 million. Revenue recognition of this amount will be spread over the initial term of the contract, i.e. 3 years.
- Government financing of research expenditures amounted to €3.0 million for the first half of 2017, stable compared to the first half of 2016. These figures included a research tax credit of €3.0 million for the first six months of 2017 compared to €2.9 million for the same period in 2016.

**Research and Development (R&D) expenses** amounted to €16.9 million for the first half of 2017 compared to €12.5 million for the same period in 2016. This increase was mainly due to the 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). External expenses for clinical projects also increased by €0.4 million with the development plan progressing notably with our products TG4010, Pexa-Vec and TG1050.

General and administrative expenses decreased to €3.1 million for the first half of 2017 compared to €3.4 million for the same period in 2016.

**Net loss** amounted to €18.4 million for the first half of 2017 compared to €12.2 million for the same period in 2016.

As of June 30, 2017, the Company's **cash, cash equivalents, available-for-sale financial assets and other financial assets** amounted to €43.9 million versus €56.2 million as of December 31, 2016.

Cash burn was €12.3 million for the first half of 2017 compared to €8.2 million for the same period in 2016. This cash burn increase was mainly explained by the milestone payment to Sillajen in H1 2017.

**Transgene confirms that it expects 2017 cash burn to be around €30 million**, which includes an increase of expenses linked to clinical trials due to the acceleration of the clinical development plan and the milestone payment to SillaJen, Inc.

"Our results for the first six months of 2017 are in line with our expectations. We confirm our financial visibility through to the end of 2018", commented Jean-Philippe Del, Chief Financial Officer of Transgene.

As a reminder, the Company still benefits from access to further additional funding that can be activated in 2017: namely the second tranche of the European Investment Bank (EIB) loan (€10 million).

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#### About Transgene

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 and preclinical development, including TG1050 (chronic hepatitis B) and TG6002 (solid tumors). 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 <u>www.transgene.fr</u>. Follow us on Twitter: <u>@TransgeneSA</u>

#### 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, 2017	Dec. 31, 2016
Current assets:		
Cash and cash equivalents	3,091	4,855
Other current financial assets	40,852	51,352
Cash, cash equivalents and other current financial assets:	43,943	56,207
Trade receivables	2,499	2,385
Inventories	194	221
Other current assets	14,094	15,242
Assets available for sale	-	-
Total current assets	60,730	74,055
Non-current assets:		
Property, plant and equipment	14,054	14,580
Intangible assets	330	423
Non-current financial assets	4,229	5,023
Investments in associates	3,625	3,923
Other non-current assets	18,900	24,946
Total non-current assets	41,138	48,895
Total assets	101,868	122,950
LIABILITIES AND EQUITY	June 30, 2017	Dec. 31, 2016
Current liabilities:		
Trade payables	4,394	4,504
Current financial liabilities	10,275	10,198
Provisions for risks	536	1,456
Other current liabilities	4,204	3,761
Total current liabilities	19,409	19,919
Non-current liabilities:		
Non-current financial liabilities	50,044	52,803
Employee benefits	3,874	3,725
Total non-current liabilities	53,918	56,528
Total liabilities	73,327	76,447
<u>Equity:</u>		
Share capital	56,432	56,432
Share premiums et reserves	504,555	504,248
Retained Earnings	(513,194)	(487 <i>,</i> 987)
Profit/(loss) for the period	(18,346)	(25,207)
Other comprehensive income/(loss)	(906)	(983)
Total equity attributable to Company shareholders	28,541	46,503
Total equity and liabilities	101,868	122,950

## Consolidated income statement, IFRS

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

	June 30, 2017	June 30, 2016
Revenue from collaborative and licensing agreements	472	1,905
Public funding for research expenses	3,028	2,970
Other income	398	464
Operating income	3,898	5,339
Research and development expenses	(16,855)	(12,504)
General and administrative expenses	(3,066)	(3,406)
Other expenses	(107)	(128)
Operating expenses	(20,028)	(16,038)
Operating income/(loss)	(16,130)	(10,699)
Net finance cost	(981)	(526)
Share of profit/(loss) of associates	(1,235)	(414)
Income/(loss) before tax	(18,346)	(11,639)
Income tax expense	-	-
Net income/(loss)	(18,346)	(11,639)
Net income/(loss) from discontinued operations	-	(514)
Comprehensive net income/(loss)	(18,346)	(12,153)
Basic loss per share (€)	(0.33)	(0.32)
Diluted earnings per share (€)	(0.33)	(0.32)

### Cash Flow statement, IFRS

(in € thousands)

	June 30, 2017	June 30, 2016
Cash flow from operating activities:		
Net income/(loss) from continuing operations	(18,346)	(11,638)
Net income/(loss) from discontinued operations	-	(514)
Cancellation of financial income	981	526
Elimination of non-cash items		
Income of associates	1,235	414
Provisions	(770)	(6,593)
Depreciation	747	1,291
Share-based payments	218	87
Other	18	6,220
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow:	(15,917)	(10,207)
Change in operating working capital requirements:		
Current receivables and prepaid expenses	(78)	(2,186)
Inventories and work in progress	27	1,013
Research tax credit (RTC)	(3,113)	(2,997)
Disposal of available-for-sale assets	-	2,000
Other current assets	1,119	(2,347
Trade payables	(408)	414
Prepaid income	1,026	(65
Employee benefits	(563)	(348
Other current liabilities	(20)	(2)
Net cash used in operating activities:	(17,927)	(14,725)
Cash flows from investing activities:		
(Acquisitions)/disposals of property, plant and equipment	160	159
(Acquisitions)/disposals of intangible assets	(10)	(4)
Other (acquisitions)/disposals	10	330
Net cash used in investing activities:	160	485
Cash flows from financing activities:		
Net financial income/(loss) proceeds	(239)	(130)
Gross proceeds from the issuance of shares	-	
Share issue costs	-	
Conditional subsidies	29	
(Acquisition)/disposal of other financial assets	10,499	605
Net amounts received for financing of tax credits	6,294	6,760
Bank borrowing	-	10,000
Financial leases	(578)	(670)
Net cash generated from/(used in) financing activities:	16,005	16,566
Effect of changes in exchange rates on cash and cash equivalents	(2)	(2)
Net increase/(decrease) in cash and cash equivalents:	(1,764)	2,324
Cash and cash equivalents at beginning of period	4,855	3,285
Cash and cash equivalents at end of period:	3,091	5,609
Investments in other current financial assets	40,852	27,760
Cash, cash equivalents and other current financial assets:	43,943	33,369