Transgene Confirms the Timeline of its Clinical News Flow and Presents 2019 Half-Year Results

- **Collaboration agreement signed with AstraZeneca: Transgene to build five Invir.IO® oncolytic viruses, each under an option and license agreement**
- **First efficacy results of the combination trial of TG4001 to be presented at ESMO on September 30, 2019**
- **First efficacy results of the combination trial of TG4010 expected in December 2019**
- **Two clinical trials with TG4050 to start in 4Q 2019, in collaboration with NEC**
- **First patient to be enrolled in a new trial with TG6002 in 4Q 2019**
- **Pexa-Vec: decision to stop development in hepatocellular carcinoma**
- **Financial visibility until 2022, following €48.7 million rights issue**

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

Strasbourg, France, September 18, 2019, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, announces its financial results for the six-month period ended June 30, 2019, and provides an update on its portfolio.

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

"Transgene has made significant progress with its new technology platforms, its clinical pipeline, and in strengthening its financial position in 2019. Our collaboration with AstraZeneca provides strong validation of the potential of the multi-armed OVs that we are developing thanks to our innovative Invir.IO® platform. I am also pleased that we have gained regulatory clearance to begin the clinical development of our lead myvac™ *individualized immunotherapy TG4050 in both the US and Europe before the end of 2019.*

Following the negative interim analysis of the PHOCUS trial of Pexa-Vec, we have decided to focus our oncolytic development efforts in indications other than hepatocellular carcinoma. We are looking forward to announcing important clinical data for our candidates TG4001, TG4010 and TG6002 before year end and initiating soon new trials with TG4050 and oncolytic products.

With financial visibility until 2022, Transgene is well placed to leverage these clinical data and move its novel OV and immunotherapy technology platforms into the clinic."

Clinical Pipeline Review

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
- ✓ Last patient enrolled in May 2019
- ✓ Clinical collaboration with Bristol-Myers Squibb, for the supply of nivolumab
- ➲ **Six-month overall response rate, on at least 35 evaluable patients, expected in December 2019**

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

HPV-positive cancers including oropharyngeal head and neck cancer – 2nd line
- ✓ Clinical collaboration with Merck KGaA and Pfizer, for the supply of avelumab
- ✓ Publication of the results of a Phase 2b trial of TG4001 in Gynecologic Oncology, demonstrating the biological activity of this immunotherapeutic in CIN 2/3 lesions; editorial in The Lancet Oncology (April 2019)
- ➲ **Poster presentation of the translational and efficacy data of the Phase 1b part of the trial at ESMO[1] (Sept. 27 - Oct. 1, 2019)**
- ➲ **Interim Phase 2 results expected in 1H 2020**

TG6002
Phase 1/2a

Gastro-intestinal adenocarcinoma (colon cancer for Phase 2) – Intravenous (IV) route
- ✓ Publication in Molecular Therapy Oncolytics highlighting the promising activity of TG6002 in preclinical colorectal carcinoma models
- ✓ Multicenter trial ongoing in Belgium, France and Spain
- ➲ **First clinical results (safety) expected at the end of the year 2019**

TG6002
Phase 1/2a

Colon cancer with liver metastasis – Intrahepatic artery (IHA) route
- ✓ Multicenter trial authorized in the United Kingdom (July 2019)
- ➲ **First patient enrolled in 4Q 2019**

TG4050 is an individualized therapeutic vaccine, based on the patient's specific tumor mutations. TG4050 is the first product candidate generated from the myvac™ *technological platform. It is being developed in collaboration with NEC, a partner that brings its know-how in artificial intelligence and co-finances two clinical trials. Through the NEOVIVA consortium, TG4050 also benefits from the support of Bpifrance.*

myvac™
TG4050
Phase 1

Ovarian cancer – after first-line surgery and adjuvant therapy
- ✓ Trial authorized in the United States (May 2019) and in France (Sept. 2019)
- ✓ Principal investigator: Matthew Block (Mayo Clinic)
- ➲ **First patient to be enrolled in 4Q 2019**

myvac™
TG4050
Phase 1

HPV-negative head and neck cancer – after surgery and adjuvant therapy
- ✓ Trial authorized in the United Kingdom (July 2019) and in France (Sept. 2019)
- ✓ Principal investigator: Christian Ottensmeier (Southampton University)
- ➲ **First patient to be enrolled in 4Q 2019**

The first oncolytic virus generated from the Invir.IO® platform is armed with BioInvent's patented anti-CTLA-4 antibody. This development program is co-financed by our partner BioInvent. Our new generation of immunotherapeutics uses an optimized Vaccinia Copenhagen *strain; it carries a double deletion TK-RR-, which makes its replication more selective. Its arming involves well-established immunotherapy mechanisms to better attack tumors by combining several complimentary mechanisms of action.*

Invir.IO®
VV-α-CTLA-4
Phase 1

Solid tumors
- ✓ Collaboration with BioInvent
- ➲ **Preclinical data to be presented at upcoming scientific conferences in 4Q 2019**
- ➲ **Regulatory filing for first-in-human trial planned in 1Q 2020**

[1] "Phase Ib/II trial of TG4001 (Tipapkinogene sovacivec), a therapeutic HPV-vaccine, and Avelumab in patients with recurrent/metastatic (R/M) HPV-16+ cancers" The Poster #1210P will be presented on September 30, 2019 by Pr Le Tourneau. The abstract will be available on the ESMO website on September 23, 2019.

Update on the development of Pexa-Vec

On August 2, 2019, Transgene announced that the Independent Data Monitoring Committee (IDMC) of the PHOCUS Phase 3 trial recommended stopping the study based on the IDMC's assessment that the trial would be unlikely to meet its primary objective at the time of the final analysis.
Transgene has reviewed the PHOCUS data; the Company has also interacted with clinicians, notably with respect to the recent failures in other first-line hepatocellular carcinoma trials. Transgene has decided to stop the ongoing trial evaluating Pexa-Vec in combination with nivolumab in this indication (first-line treatment of advanced liver cancer), which remains a hard-to-treat disease.

Key events of the period

Invir.IO®: Collaboration agreement with AstraZeneca and extension of the collaboration with BioInvent

Transgene and AstraZeneca signed a collaboration agreement with exclusive license options with the aim to codevelop five new multifunctional oncolytic viruses based on the Invir.IO® platform. Transgene received $10 million (€8.9 million) payment upon signing. The company could also receive up to $3 million payments based on the preclinical development milestones and an option exercise payment for each candidate in the event AstraZeneca exercises its license option, as well as development and commercial milestones and royalties (press release distributed on May 2, 2019). **In March 2019, Transgene extended its collaboration with BioInvent** for the development of new oncolytic viruses encoding for undisclosed antibody sequences capable of treating a broad range of solid tumors.

myvac™ platform: agreement finalized with NEC and support from Bpifrance

In January 2019, Transgene and NEC finalized their collaboration agreement. NEC is applying its Artificial Intelligence (AI) "NEC the Wise" technology to TG4050, the first individualized immunotherapeutic derived from the *myvac*™ platform. This AI has been developed by NEC for several years in the field of oncology; it will be used to analyze the mutational profiles of the patients' tumors and select the most relevant mutations that will be integrated in the therapeutic vaccine. This collaboration combines Transgene's expertise in viral vectors with the power of NEC's AI. Thanks to this collaboration, therapeutic vaccination is entering the digital age, allowing the design of individualized treatments to fight against cancer. NEC is also cofinancing 50% of the first two clinical trials of TG4050. **In March 2019, the NEOVIVA project was selected by the "Investments for the Future" Program** (Programme d'Investissements d'Avenir) operated by Bpifrance for the development of the *myvac*™ platform. The NEOVIVA project has been granted €5.2 million over five years, of which Transgene is allocated €2.6 million. The NEOVIVA project aims at strengthening the development of an industrial sector focused on this innovative technology together with three partners: HalioDx, Traaser and Institut Curie. The NEOVIVA project is complimentary to the collaboration between Transgene and NEC.

€48.7 million rights issue completed in July 2019

On June 14, 2019, Transgene announced a €48.7 million share capital increase through a rights issue with preferential subscription rights, extending the Company's financial visibility until 2022. This transaction was completed on July 2, 2019; the settlement and delivery of the shares were executed on July 4, 2019. After the rights issue, the Institut Mérieux (through its subsidiary TSGH) and Dassault Belgique Aviation respectively own 60.44% and 4.98% of Transgene's equity.

€20 million credit line from Natixis

Transgene obtained a renewable €20 million credit line from Natixis. The credit facility has a 30-month term and Transgene is able to draw down on and repay the facility at its discretion until July 2021. Transgene has used its shares in the Chinese biotech company Tasly Biopharmaceuticals as collateral for this loan. On June 24, 2019, Tasly Biopharmaceuticals filed its draft initial public offering document with the Hong Kong Stock Exchange. To date, the Company had not drawn down on this credit facility.

Key Financials

Key elements of the income statement

(in thousands of euros)	**June 30, 2019**	**June 30, 2018**
Operating revenues	**4,909**	**3,548**
Research and development expenses	(14,668)	(13,764)
General and administrative expenses	(3,572)	(2,963)
Other expenses	(141)	(82)
Operating expenses	**(18,381)**	**(16,809)**
Operating income/(loss)	**(13,472)**	**(13,261)**
Net income/(loss)	**(15,342)**	**(14,873)**

Operating revenues amounted to €4.9 million for the first six months of 2019 compared to €3.6 million for the same period in 2018.

- Revenues from collaboration and licensing agreements amounted to €1.5 million for the first six months of 2019 versus €0.6 million in the same period in 2018. Under the collaboration agreement with AstraZeneca on Invir.IO® program, Transgene received, in May 2019, a €8.9 million payment. This initial payment is recognized in income against the progress of the associated activities until 2020. As of June 30, 2019, the income recognized was €0.7 million.
- The research tax credit amounted to €3.1 million for the first half of 2019, compared to €2.8 million for the first half of 2018.

Research and Development (R&D) expenses amounted to €14.7 million in the first half of 2019 compared to €13.8 million for the same period in 2018. External expenses for clinical projects increased to €4.7 million from €3.8 million in the first half of 2018, as we continued to progress the clinical development of our products.

General and administrative expenses amounted to €3.6 million for the first half of 2019 compared to €3.0 million for the same period in 2018.

Net loss amounted to €15.3 million for the first half of 2019 compared to €14.9 million for the same period in 2018.

As of June 30, 2019, the Company's **cash, cash equivalents and other financial assets** amounted to €12.8 million versus €16.9 million as of December 31, 2018. In addition, Transgene received the net proceed of the rights issue (€47.1 million) on July 4, 2019, which significantly strengthened the Company's cash position. Transgene's cash burn amounted to €4.1 million in the first half of 2019, compared with €8.3 million for the same period in 2018.

Transgene confirms its **net cash burn target of approximately €20 million for 2019.**

"Our financials for the first half of 2019 are in line with our expectations as we continue to progress our clinical and preclinical assets. The success of our rights issue in June and July 2019 has extended our financial visibility until 2022," commented Jean-Philippe Del, Chief Financial Officer of Transgene.

The Board of Directors of Transgene met on September 18, 2019, and adopted the financial statements for the six-month period ended June 30, 2019. 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 18th, 2019, at 6:30 p.m. CET.

Webcast link to English language conference call:
https://channel.royalcast.com/webcast/transgene/20190918_1/

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Confirmation code: Transgene

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 (Euronext: TNG) is a publicly traded French biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. 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, TG4001, a therapeutic vaccine against HPV-positive cancers, and TG6002, an oncolytic virus for the treatment of solid tumors.
With its proprietary platform Invir.IO®, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses.
myvac™, an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the *myvac*™ platform, will enter the clinic for the treatment of ovarian cancer and head and neck cancer.
Additional information about Transgene is available at www.transgene.fr.
Follow us on Twitter: @TransgeneSA

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, 2019**	**Dec. 31, 2018**
Current assets:		
Cash and cash equivalents	11,709	1,885
Other current financial assets	1,081	15,015
Cash, cash equivalents and other current financial assets	**12,790**	**16,900**
Trade receivables	914	784
Inventories	418	443
Other current assets	10,321	11,627
Total current assets	**24,443**	**29,754**
Non-current assets:		
Property, plant and equipment	13,685	13,321
Intangible assets	165	180
Non-current financial assets	44,313	45,158
Investments in associates	-	-
Other non-current assets	11,214	20,234
Total non-current assets	**69,377**	**78,893**
Total assets	**93,820**	**108,647**

LIABILITIES AND EQUITY	**June 30, 2019**	**Dec. 31, 2018**
Current liabilities:		
Trade payables	5,820	4,791
Current financial liabilities	8,119	11,313
Provisions for risks	11	76
Other current liabilities	11,452	3,463
Total current liabilities	**25,402**	**19,643**
Non-current liabilities:		
Non-current financial liabilities	42,181	48,369
Employee benefits	3,942	3,778
Other non-current liabilities	647	158
Total non-current liabilities	**46,770**	**52,305**
Total liabilities	**72,172**	**71,948**
Equity:		
Share capital	62,449	62,276
Share premiums and reserves	12,673	512,581
Retained Earnings	(37,444)	(545,473)
Profit/(loss) for the period	(15,342)	8,029
Other comprehensive income/(loss)	(688)	(714)
Total equity attributable to Company shareholders	**21,648**	**36,699**
Total equity and liabilities	**93,820**	**108,647**

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

	June 30, 2019	June 30, 2018
Revenue from collaborative and licensing agreements	1,463	605
Public funding for research expenses	3,132	2,837
Other income	314	106
Operating income	**4,909**	**3,548**
Research and development expenses	(14,668)	(13,764)
General and administrative expenses	(3,572)	(2,963)
Other expenses	(141)	(82)
Net operating expenses	**(18,381)**	**(16,809)**
Operating income/(loss)	**(13,472)**	**(13,261)**
Net finance cost	(1,870)	(1,109)
Share of profit/(loss) of associates	-	(503)
Income (loss) before tax	**(15,342)**	**(14,873)**
Income tax expense	-	-
Comprehensive net income/(loss)	**(15,342)**	**(14,873)**
Basic loss per share (€)	(0.25)	(0.24)
Diluted earnings per share (€)	(0.25)	(0.24)

Cash Flow statement, IFRS
(in € thousands)

	June 30, 2019	June 30, 2018
Cash flow from operating activities:		
Net income/(loss)	(15,342)	(14,873)
Cancellation of financial income	1,870	1,109
Elimination of non-cash items		
Income of associates	-	503
Provisions	70	(184)
Depreciation	(72)	1,021
Share-based payments	290	202
Other	51	11
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow:	**(13,133)**	**(12,211)**
Change in operating working capital requirements:		
Current receivables and prepaid expenses	(673)	1,046
Inventories and work in progress	25	(44)
Research tax credit (RTC)	(3,110)	(2,914)
Other current assets	2	289
Trade payables	939	996
Prepaid income	8,059	(179)
Employee benefits	417	79
Other current liabilities	2	236
Net cash used in operating activities:	**(7,472)**	**(12,702)**
Cash flows from investing activities:		
(Acquisitions)/disposals of property, plant and equipment	(210)	(1,243)
(Acquisitions)/disposals of intangible assets	(24)	(25)
Other (acquisitions)/disposals	1,106	891
Net cash used in investing activities:	**872**	**(377)**
Cash flows from financing activities:		
Net financial income/(loss) proceeds	(205)	(69)
Conditional subsidies	-	30
(Acquisition)/disposal of other financial assets	13,934	11,120
Net amounts received for financing of tax credits	5,500	4,669
Bank borrowing	(2,250)	-
Financial leases and change in lease obligations	(556)	87
Net cash generated from/(used in) financing activities:	**16,423**	**15,837**
Exchange rates on cash and cash equivalents	1	1
Net increase/(decrease) in cash and cash equivalents:	**9,824**	**2,759**
Cash and cash equivalents at beginning of period	1,885	1,643
Cash and cash equivalents at end of period:	**11,709**	**4,402**
Investments in other current financial assets	1,081	28,642
Cash, cash equivalents and other current financial assets:	**12,790**	**33,044**