

Major R&D milestones achieved in 2019 and strong clinical activity in 2020

- *Multiple milestones achieved in 2019, allowing the first myvac[®] and Invir.IO[™] based candidates to enter the clinic*
- *Clinical results expected in the coming months for TG4001 and TG6002*
- *Successful collaborations with AstraZeneca and NEC highlighting the quality of the new platforms, Invir.IO[™] and myvac[®] respectively*

Conference call scheduled today at 6:00 p.m. CET (in English)

Strasbourg, France, March 11, 2020, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, publishes its financial results for 2019 and provides an update on its product portfolio.

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

“We achieved multiple important advances with our novel myvac[®] and Invir.IO[™] platforms during the course of 2019. We completed all the regulatory steps required to start the US and European clinical trials of TG4050, the first individualized therapeutic vaccine based on the myvac[®] platform in January 2020. The clinical development is being co-funded by our partner NEC.

Our collaboration with AstraZeneca, based on our Invir.IO[™] platform, is progressing well with the first multifunctional oncolytic viruses already being delivered to them. This platform has also generated a number of exciting new oncolytic candidates, including BT-001, which is being co-developed with BioInvent. The preclinical results generated with BT-001 have been remarkable and we are working hard to make sure we can take our first multifunctional Invir.IO[™] oncolytic into the clinic before the end of 2020.

On the clinical front, we had a year of contrasts with on the one hand, the very encouraging initial results of TG4001, which were presented at ESMO 2019, and on the other hand, the disappointing outcome of the Phase 2 trial of TG4010 and the decision to stop Pexa-Vec trials in HCC.

We remain confident in the potential of our four clinical assets TG4001, TG4050, TG6002 and BT-001 as well as in our highly innovative technologies and platforms myvac[®] and Invir.IO[™].

We also have sufficient financial visibility to pursue our developments with determination and confidence.”

2020: multiple clinical milestones expected

Transgene's portfolio currently consists of four immunotherapy drug candidates in clinical development:

- **Two therapeutic vaccines: TG4001** currently being evaluated in a Phase 2 trial and **TG4050**, the first individualized treatment based on the *myvac*[®] platform, assessed in two Phase 1 trials.
- **Two oncolytic viruses: TG6002**, which is being assessed in two Phase 1/2a trials, and **BT-001**, the first oncolytic virus based on the Invir.IO™ platform, and which is expected to enter the clinic before the end of 2020.

Clinical results for TG4001 and TG6002 are expected in the second quarter of 2020:

- The Phase 2 trial of TG4001 in combination with avelumab in HPV-positive cancers is ongoing. Patient recruitment is in line with projections and interim results are expected in the second quarter of 2020.
- The Phase 1 trial of TG6002 administered intravenously in patients with gastrointestinal cancers is ongoing. First data are also expected in the second quarter of 2020.

With *myvac*[®] and Invir.IO™, Transgene has two next-generation platforms whose potential has been validated by collaboration deals with NEC and AstraZeneca respectively:

myvac[®] platform

- Transgene is developing the therapeutic vaccine TG4050, together with NEC. This is the first individualized vaccine based on the *myvac*[®] platform. It integrates NEC's Artificial Intelligence technologies. These technologies are used to select the most relevant mutations (neoantigens) that are integrated into the TG4050 vaccine. These AI technologies will also contribute to the in-depth analysis of the patient's immune characteristics, in order to determine the profiles of those who responded to the vaccine.
- Data validating the vaccine design principle behind TG4050 are being actively promoted and will be presented at several specialized international congresses.
- The first clinical trials assessing TG4050 are ongoing in Europe and in the United States. They are including patients with ovarian cancers and head and neck cancers. NEC is financing 50% of their cost.
- The clinical trials are a central part of a broad program of translational research in collaboration with expert centers both in the US and Europe. This program will generate a significant body of data evaluating the activity of TG4050 from these initial clinical trials. The first data are expected in 1H 2021.
- The Company has set up an in-house good manufacturing practice (GMP) unit dedicated to the manufacturing of the individualized batches of TG4050 needed for the current Phase 1 trials.
- The *myvac*[®] project is supported by Bpifrance, within the NEOVIVA program. The NEOVIVA project aims to strengthen the development of this highly innovative technology together with three partners: HaliuDx, Traaser and Institut Curie. €2.6 million have been allocated to Transgene over five years. The NEOVIVA project is complimentary to the collaboration between Transgene and NEC.

Invir.IO™ platform

- BT-001 is the first oncolytic virus from the Invir.IO™ platform. It is based on Transgene's patented viral vector VV_{cop}TKRR' which has been designed to encode BioInvent's anti-CTLA4 antibody (an immune checkpoint inhibitor) as well as the cytokine GM-CSF.
- Preclinical results with BT-001 have been extremely promising, with treatment leading to the eradication of tumors in several murine models known for their low sensitivity to immune checkpoint inhibitors. These data will be presented at scientific congresses in the coming months. A first-in-human trial is being prepared and BT-001 is expected to enter the clinic before the end of 2020.
- The collaboration with AstraZeneca is highly productive with Transgene already delivering the first multi-armed oncolytic viruses to its partner. As a result, Transgene has received \$10 million at the time the collaboration was signed and booked €1.3 million related to the achievement of certain preclinical milestones. In 2020, Transgene will continue to design further oncolytic viruses for this collaboration. AstraZeneca can exercise an option to further develop each of these novel drug candidates.

- Transgene's patented viral vector, which underpins the Invir.IO™ platform, allows the development of a wide range of multifunctional oncolytic viruses. Transgene has already designed a number of proprietary oncolytic viruses that are being evaluated in preclinical models. A candidate is expected to be selected with the aim of submitting a clinical trial application in 2H 2020 ahead of starting a clinical trial in 2021.

Summary of key ongoing clinical trials

TG4001

+ **Bavencio®**
(avelumab)
Phase 2

Targets: HPV16 E6 and E7 oncoproteins

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](#) (April 2019), demonstrating the biological activity of this immunotherapeutic in CIN 2/3 lesions; editorial in [The Lancet Oncology](#) (April 2019)
- ✓ **Positive results of the Phase 1b part of the trial presented at ESMO** (Sept. 2019)
Three of the six patients who received the recommended dose responded to the treatment. The observed responses were durable.
- ➡ **Interim Phase 2 results expected in 2Q 2020**

myvac®

TG4050

Phase 1

Targets: tumor neoantigens

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 enrolled in January 2020
- ➡ **First data expected in 1H 2021**

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 enrolled in January 2020
- ➡ **First data expected in 1H 2021**

TG6002

Phase 1/2a

Payload: FCU1 for the local production of a chemotherapy agent

Gastro-intestinal adenocarcinoma (colorectal cancer for Phase 2) – Intravenous (IV) route

- ✓ Publication in [Molecular Therapy Oncolytics](#) (March 2019) highlighting the promising activity of TG6002 in preclinical colorectal carcinoma models
- ✓ Multicenter trial ongoing in Belgium, France and Spain
- ✓ Last dose levels currently being evaluated (Phase 1 part)
- ➡ **First results of the Phase 1 part expected in 2Q 2020**

TG6002

Phase 1/2a

Colorectal cancer with liver metastasis – Intrahepatic artery (IHA) route

- ✓ Multicenter trial authorized in the United Kingdom (July 2019)
- ✓ First patient treated in February 2020
- ➡ **First results expected in 1H 2021** (Phase 1 part)

Invir.IO™

BT-001

Phase 1/2

Payload: anti-CTLA4 antibody and GM-CSF cytokine

Solid tumors

- ✓ Collaboration with BioInvent
- ✓ First clinical trial application submitted
- ➡ **Presentation of very encouraging preclinical results at upcoming scientific congresses**
- ➡ **First clinical trial expected to start before the end of 2020**

Key financials for 2019

- **Operating income of €13.7 million in 2019**, compared to € 42.9 million in 2018.
R&D services for third parties amounted to €6.7 million in 2019 (€1.3 million in 2018). This significant increase is mainly due to the collaboration signed with AstraZeneca in 2019. This generated €5.3 million in revenue in 2019. The research tax credit amounted to €6.5 million in 2019 (€5.7 million euros in 2018). As a reminder, the much higher operating income figure in 2018 was mainly the result of the €35.6 million income generated by the transaction with Tasly Biopharmaceuticals Co, Ltd.
- **Net operating expenses of €39.2 million in 2019**, compared to €35.5 million in 2018.
R&D expenses increased to €31.4 million in 2019 (from €27.3 million in 2018), due to the acceleration of external expenses for clinical projects and the setup of manufacturing unit dedicated to small clinical batches. General and administrative expenses stood at €7.1 million in 2019 versus €7.0 million in 2018.
- **Financial income of €6.7 million in 2019** versus a loss of €2.0 million in 2018.
The decision taken at the end of 2019 to stop the clinical development of TG4010 has led to a downward reassessment of the financial debt related to the repayable advances of the ADNA program of €8.7 million. This has been recognized as financial income.
- **Net loss of €18.8 million in 2019**, compared to a net profit of €8.0 million in 2018.
- **Cash burn reduced to €20.5 million in 2019** (excluding the proceeds of the rights issue), versus €24.5 million in 2018.
Transgene received €8.9 million in June 2019, following the signing of the contract with AstraZeneca. This contributed to the reduced net cash burn compared to 2018 despite an increase in operating expenses during the period.
- **Cash available at year-end 2019: €43.3 million**, compared to €16.9 million at the end of 2018, due to the successful **€48.7 million rights issue completed in July 2019**.
- Transgene expects its cash burn for 2020 to be around €25 million.

The financial statements for 2019 as well as management's discussion and analysis are attached to this press release (Appendices A and B).

The Board of Directors of Transgene met on March 11, 2020, under the chairmanship of Philippe Archinard and closed the 2019 financial statements. Audit procedures have been performed by the statutory auditors and the delivery of the auditors' report is ongoing.

The Company's universal registration document, which includes the annual financial report, will be available early April 2020 on Transgene's website, www.transgene.fr.

A conference call in English is scheduled today, March 11, 2020, at 6:00 p.m. CET.

Webcast link to English language conference call:

https://channel.royalcast.com/webcast/transgene/20200311_1/

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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 cancer cells.

The Company's clinical-stage programs consist of two therapeutic vaccines (TG4001 for the treatment of HPV-positive cancers, and TG4050, the first individualized therapeutic vaccine based on the *myvac*[®] platform) as well as two oncolytic viruses (TG6002 for the treatment of solid tumors, and BT-001, the first oncolytic virus based on the Invir.IO[™] platform).

With Transgene's *myvac*[®] platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The *myvac*[®] approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.

With its proprietary platform Invir.IO[™], Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses. Transgene has an ongoing Invir.IO[™] collaboration with AstraZeneca.

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

Follow us on Twitter: [@TransgeneSA](https://twitter.com/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.

Appendix A: Financial statements 2019**CONSOLIDATED BALANCE SHEET, IFRS***(in € thousands)*

	December 31, 2019	December 31, 2018
Assets		
CURRENT ASSETS		
Cash and cash equivalents	1,343	1,885
Other current financial assets	42,028	15,015
Cash, cash equivalents and other current financial assets	43,371	16,900
Trade receivables	2,324	784
Other current assets	3,943	12,070
Total current assets	49,638	29,754
NON-CURRENT ASSETS		
Property, plant and equipment	13,283	13,321
Intangible assets	147	180
Financial fixed assets	42,931	45,158
Investments in associates	-	-
Other non-current assets	9,478	20,234
Total non-current assets	65,839	78,893
Total ASSETS	115,477	108,647
	December 31, 2019	December 31, 2019
Liabilities and equity		
CURRENT LIABILITIES		
Trade payables	7,092	4,791
Financial liabilities	2,037	11,313
Provisions for risks	898	76
Other current liabilities	8,619	3,463
Total current liabilities	18,646	19,643
NON-CURRENT LIABILITIES		
Financial liabilities	26,703	48,369
Employee benefits	4,427	3,778
Other non-current liabilities	4	158
Total non-current liabilities	31,134	52,305
Total liabilities	49,780	71,948
EQUITY		
Share capital	83,265	62,276
Share premiums and reserves	39,738	512,581
Retained earnings	(37,444)	(545,473)
Profit (loss) for the period	(18,804)	8,029
Other comprehensive income	(1,058)	(714)
Total equity attributable to Company shareholders	65,697	36,699
TOTAL LIABILITIES AND EQUITY	115,477	108,647

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

	December 31, 2019	December 31, 2018
Revenue from collaborative and licensing agreements	6,652	1,335
Government financing for research expenditure	6,644	5,749
Other income	437	35,835
Operating income	13,733	42,919
Research and development expenses	(31,385)	(27,342)
General and administrative expenses	(7,134)	(6,991)
Other expenses	(668)	(1,211)
Net operating expenses	(39,187)	(35,544)
Operating income	(25,454)	7,375
Finance cost	6,650	(2,021)
Share of profit (loss) of associates	-	2,675
Income (loss) before tax	(18,804)	8,029
Income tax expense	-	-
NET INCOME	(18,804)	8,029
Basic loss per share (€)	(0,23)	0,13
Diluted earnings per share (€)	(0,23)	0,13

Cash Flow statement, IFRS
(in € thousands)

	December 31, 2019	December 31,2018
Cash flow from operating activities		
Net income/(loss)	(18,804)	8,029
Cancellation of financial income	(6,650)	2,021
Elimination of non-cash items		
Income of associates	-	(2,675)
Provisions	993	(333)
Depreciation	770	2,043
Share-based payments	1,351	467
Others	1,066	(35,590)
Net cash generated from/(used in) operating activities before change in working capital and other operating cash flow	(21,274)	(26,038)
Change in operating working capital requirements		
Current receivables and prepaid expenses	(1,269)	2,268
Inventories and work in progress	443	(173)
Research tax credit	(6,619)	(5,899)
Other current assets	(962)	(23)
Trade payable	2,270	2,031
Prepaid income	4,461	(368)
Other current liabilities	537	138
Net cash used in operating activities	(22,413)	(28,064)
Cash flows from investing activities		
(Acquisitions)/disposals of property, plant and equipment	(1,688)	(1,359)
(Acquisitions)/disposals of intangible assets	(43)	(45)
Other (acquisitions)/disposals	1,200	6
Net cash used in investing activities	(531)	(1,398)
Cash flow from financing activities		
Net financial income proceeds	(980)	(79)
Gross proceeds from the issuance of shares	48,710	-
Share issue costs	(1,763)	-
Conditional subsidies	237	30
(Acquisitions)/disposal of other financial assets	(26,904)	24,790
Net tax credit financing	6,706	5,666
Bank loan	(2,371)	-
Financial leases and change in lease obligations	(1,234)	(704)
Net cash generated from/(used in) financing activities	22,401	29,703
Effect of changes in exchange rates on cash and cash equivalents	1	1
Net increase/(decrease) in cash and cash equivalents	(542)	242
Cash and cash equivalents at beginning of period	1,885	1,643
Cash and cash equivalents at end of period	1,343	1,885
Investments in other current financial assets	42,028	15,015
Cash, cash equivalent and other current financial assets	43,371	16,900

Appendix B: Management Discussion of 2019 Financials

Revenue

During the period under review, income from collaboration and licensing agreements, represented €6.7 million in 2019 versus €1.3 million in 2018. This consisted primarily of the following items:

- research and development services for third parties amounting to €6.6 million in 2019 (€1.3 million in 2018), mainly due to €5.3 million in revenue being recognized from the collaboration with AstraZeneca over the period; and
- income related to the commercial use of technologies or products provided under license by Transgene amounting to €0.06 million in 2019 compared to €0.03 million in 2018.

Public funding for research expenses accounted for €6.6 million in 2019 versus €5.7 million in 2018. This is mainly due to the research tax credit and to grants received and receivable:

- the research tax credit (CIR - crédit impôt recherche) amounted to €6.5 million in 2019 (€5.7 million in 2018); and
- research grants amounted to less than €0.1 million in 2018. There were none in 2018.

Other income

Other income amounted to €0.4 million in 2019 versus €35.8 million in 2018. This decrease is attributable to the sale of rights in TG1050 for Greater China to Tasly BioPharmaceuticals Co., Ltd. for €35.6 million in July 2018.

Operating expenses

Research and development (R&D) expenses

R&D expenses amounted to €31.4 million in 2019 versus €27.3 million in 2018.

The following table details R&D expenses by type:

<i>(In millions of euros)</i>	Dec. 31, 2019	Dec. 31, 2018
Payroll costs	11.2	11.2
Share-based payments	0.9	0.3
Intellectual property expenses and licensing costs	0.8	0.9
External expenses for clinical projects	10.9	7.9
External expenses for other projects	1.6	1.5
Operating expenses	4.2	3.7
Depreciation and provisions	1.8	1.8
RESEARCH AND DEVELOPMENT EXPENSES	31.4	27.3

Employee costs allocated to R&D (salaries, employer contributions and related expenses) amounted to €11.2 million in 2019, the same level as in 2018.

Share-based payments amounted to €0.9 million in 2019 compared to €0.3 million in 2018. This increase is due to two distributions of free shares to employees in 2019.

External expenses for clinical projects amounted to €10.9 million in 2019, compared to €7.9 million in 2018. This increase is explained by the launch of new clinical trials in 2019 and by the continuation of ongoing clinical trials. Following the decision to stop the development of TG4010, the remaining €0.9 million costs related to the ongoing clinical trial with this product were fully provisioned in 2019.

Other external expenses, including expenses for research and preclinical activities, were €1.6 million in 2019, versus 1.5 million in 2018.

Operating expenses, including the cost of operating research laboratories, amounted to €4.2 million in 2019, compared to €3.7 million in 2018.

General and administrative (G&A) expenses

General and administrative (G&A) expenses amounted to €7.1 million in 2019 versus €7.0 million in 2018.

The following table details G&A expenses by type:

<i>(In millions of euros)</i>	Dec. 31, 2019	Dec. 31, 2018
Payroll costs	3.2	3.3
Share-based payments	0.4	0.2
Fees and administrative expenses	2.8	2.8
Other fixed costs	0.6	0.6
Depreciation and provisions	0.1	0.1
GENERAL AND ADMINISTRATIVE EXPENSES	7.1	7.0

Employee costs allocated to G&A stood at €3.2 million in 2019, compared to €3.3 million in 2018.

Fees and administrative expenses are stable at €2.8 million.

Other expenses

Other expenses decreased to €0.7 million in 2019 compared to €1.2 million in 2018. This reduction is mainly related to the Company's decision to no longer recognize inventories on the balance sheet, resulting in an expense of €0.4 million for the period.

Financial income

Net financial income stood at €6.7 million in 2019 versus a net loss of €2.0 million in 2018.

Financial income amounted to €9.9 million in 2019 (compared to €0.3 million in 2018), and mainly consisted of:

- a downward reassessment of the financial debt owed to Bpifrance on the advances received under the ADNA program following the decision to stop the development of TG4010 (€8.7 million income in 2019, versus a €1.0 million loss in 2018);
- the discounting of the debt owed to Bpifrance on the NEOVIVA program (€0.08 million in 2019); and
- the interest on financial investment income, which was stable at €0.1 million in 2019.

Financial expenses amounted to €3.2 million in 2019 (€2.0 million in 2018) and were mainly related to:

- bank interest on the loan received from the EIB (€0.8 million, as was the case in 2018)
- the present discounting of the contingent proceeds on the sale of Jennerex, Inc. stock to SillaJen, Inc. in 2014 (€0.3 million, as in 2018);
- interest related to the sale of research tax credit receivables (€0.3 million);
- the interest on financial leases (€0.2 million in 2018, the same as in 2018).

Net income (loss)

The net loss was €18.8 million in 2019, compared with a net profit of €8.0 million in 2018.

The net loss was €0.23 per share in 2019 versus net earnings of €0.13 per share in 2018.

Investments

Investments in tangible and intangible assets (net of disposals) increased to €1.1 million in 2019 (€0.5 million in 2018).

Repayable advances and loans

Since 2016, Transgene has benefited from a credit facility granted by the European Investment Bank (EIB) of €10 million. This loan is payable in 2021. The accrued interest of €2.3 million for the first 3 years was paid during the first half of 2019.

In April 2019, the Company signed a revolving credit agreement with Natixis for a maximum of €20 million, which can be drawn down in one or more installments. Under this credit agreement, Transgene must pledge the shares it holds in Tasly BioPharmaceuticals prior to the first drawdown. This credit agreement is valid until June 2022 and, according to the principles of a revolving credit, the capital drawn down must be fully repaid at the latest at the end of the program's duration. The Company has not drawn on this credit facility in 2019.

In 2019, Transgene has participated as a leader in a new research program, NEOVIVA, supported by Bpifrance. The Company could receive up to €2.6 million (€0.2 million in grants, €2.4 million in repayable advances) over a five-year period starting in 2019.

Liquidity and capital resources

The Company's cash is invested in short-term money-market mutual funds or placed, at market conditions, in a cash pool managed by the majority shareholder of Transgene, Institut Mérieux.

At December 31, 2019, the Company had €43.3 million in cash available, compared with €16.9 million at December 31, 2018.

Cash burn

The Company's net cash burn amounted to €20.5 million in 2019 versus €24.5 million in 2018.

Post-closing events

N/A