

Snippet roundup: Roche gets Impassioned in breast cancer but Genomic Vision's future dims



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Welcome to your weekly roundup of *EP Vantage's* snippets – short takes on smaller news items.

This week, July 2-6, 2018, we had thoughts on the following: Genomic Vision loses sight of its market; a fair wind blows for Pulmonx; Impassion-130 marks a breast cancer first for immuno-oncology.

These snippets were previously published daily via [twitter](#).

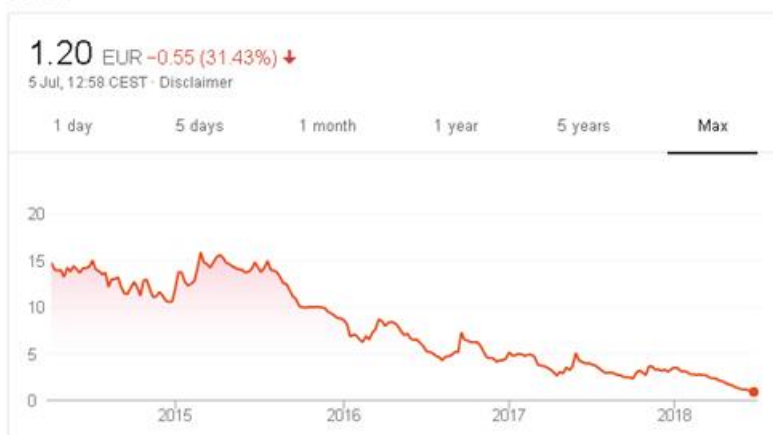
Genomic Vision loses sight of its market

July 5, 2018

In 2016 Genomic Vision altered its business model drastically, from selling *in vitro* diagnostics to providing life science research tools. This appears to have been a bad move. The French company has issued a profit warning, having failed to sell any of its FiberVision machines in the second quarter. The 31% share price plunge on Euronext Paris this morning means that since its IPO in April 2014, Genomic Vision has haemorrhaged 95% of its value. FiberVision is a platform technology that uses what Genomic Vision calls “molecular combing” – stretching out single DNA molecules onto specially treated glass coverslips – which the company intended to sell to test manufacturers or researchers. The company also sells one diagnostic test, for facio-scapulo-humeral dystrophy, directly in Europe; in the US this is sold by Quest Diagnostics under a partnership agreement, though in March 2017 analysts from Société Générale wrote that “Quest now no longer seems committed to its partnership with GV”. In the short term Genomic Vision will keep itself going by dipping into the €10m (\$8.6m) convertible bond that it obtained two years ago. After that, perhaps a pivot back to the IVD business might be for the best, though with its next most advanced being a BRCA test for breast and ovarian cancers the competitive landscape does not look good.

Genomic Vision SA

EPA: GV



Source: Google finance

A fair wind blows for Pulmonx

July 2, 2018

Pulmonx has been going for 23 years and has five 510(k) clearances to show for it. It can now boast its first FDA premarket approval, and this will surely come as a breath of fresh air to the backers who have pumped nearly \$140m into the group over the years. The Zephyr Endobronchial Valve is implanted into the lungs to treat the breathing difficulty that characterises severe emphysema. Emphysema damages alveoli, and this can cause air to become trapped in the lungs during exhalation. The patient cannot then inhale enough new air. To

treat this, three to five Zephyrs are placed in the lungs of each patient using a bronchoscope during a procedure that lasts 30-60 minutes. Each valve closes during inhalation to prevent air from entering the damaged parts of the lung and opens during exhalation, allowing trapped air and fluids to escape. It is intended to be used in patients in whom drug therapy has failed, the hope being that it will be a less invasive - and cheaper - therapy than surgery.

Pulmonx's VC funding

Date	Round	Investment (\$m)	Investors
Mar 2017	Series F	50.0	Undisclosed
Apr 2014	Series E	10.0	Undisclosed
Feb 2012	Series D	10.0	Undisclosed
Feb 2010	Series C	32.0	DeNovo Ventures; HealthCap; Kleiner Perkins Caufield and Byers; Latterell Venture Partners; MedVenture Associates; Montreux Equity Partners; POSCO BioVentures
May 2007	Series B	20.0	De Novo Ventures; Latterell Venture Partners; MedVenture Associates; Montreux Equity Partners
Nov 2003	Series A	7.0	MedVenture Associates; Montreux Equity Partners
Nov 2000	Seed Capital	8.3	Tyco International
	Total	137.3	

Source: EvaluateMedTech.

Impassion-130 marks a breast cancer first for immuno-oncology

July 2, 2018

It is thanks to Roche's established presence in breast cancer that the Swiss company has the most advanced pivotal programme of any immuno-oncology group in the tough to treat triple-negative type of this disease. Today an interim analysis of the first of seven Tecentriq phase III studies in this setting, Impassion-130, read out positively for progression-free survival; the overall survival co-primary endpoint is still immature. Impassion-130 pitted Tecentriq plus Abraxane against first-line disease; two ongoing trials test the Roche drug front line with chemo, three others are in neoadjuvant use and one is in the adjuvant setting. The only other anti-PD-(L)1 MAb in company-sponsored pivotal triple-negative breast cancer trials is Merck & Co's Keytruda: Keynote-522 in neoadjuvant use and Keynote-119 in late-line treatment should yield data this year. Another pillar of Roche's attack on triple-negative disease is its little-appreciated Akt inhibitor ipatasertib, licensed from Array - ipatasertib's phase III Ipatunity-130 study started recruitment in the first quarter. Full data from Impassion-130 might be presented at Esmo in October, along with the Impower-133 small-cell lung cancer trial that read out positively last month, making the European cancer meeting key for the Swiss group.

Phase III studies of anti-PD-(L)1 MABs in triple-negative breast cancer

Treatment	Sponsor	Setting	Primary endpoint	Study	Trial ID	Primary completion
Keytruda + chemo	Merck & Co	Neoadjuvant	Pathological CR, event-free survival	Keynote-522	NCT03036488	Nov 2018
Keytruda vs chemo	Merck & Co	2nd or 3rd-line	OS	Keynote-119	NCT02555657	Dec 2018
Tecentriq + paclitaxel	Roche	1st-line	PFS	Impassion-131	NCT03125902	Feb 2019
Tecentriq + chemo	Roche	Neoadjuvant	Pathological CR	Impassion-031	NCT03197935	Mar 2019
Tecentriq + chemo	Roche	1st-line	OS	Impassion-132	NCT03371017	Jun 2019
Keytruda + chemo	Merck & Co	1st-line	OS, PFS, safety (by PD-L1 status)	Keynote-355	NCT02819518	Dec 2019
Tecentriq + Abraxane	Roche	1st-line	OS, PFS (by PD-L1 status)	Impassion-130	NCT02425891	Apr 2020
Bavencio	Istituto Oncologico Veneto IRCCS	Adjuvant	Invasive disease-free survival	A-Brave	NCT02926496	Jun 2021
Tecentriq + chemo	Roche	Adjuvant	Disease-free survival (by PD-L1 status)	Impassion-030	NCT03498716	Jan 2022
Tecentriq + Abraxane	Fondazione Michelangelo	Neoadjuvant	Event-free survival	NeoTRIPaPDL1	NCT02620280	May 2022
Tecentriq + chemo	Roche	Neoadjuvant	Pathological CR, event-free survival	MO39875	NCT03281954	Dec 2023

Source: ClinicalTrials.gov.

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