



# European Biotechnology

ISSN 2364-2351 | A 60711 | BIOCOM

Life Sciences and  
Industry **Magazine**

Summer Edition 2016 | Volume 15 | 20 €

## Interview

Richard Mason,  
the new head of  
J&J's Innovation  
Centre in London,  
talks about early  
external know-  
how sourcing



## Cancer Immunotherapy



**FREE EXCERPT**

# Natural Born Killers

### Financing in Europe

Good numbers, but investors  
are anxious about the future

### Adaptive Pathways

Testing the new superhighway  
to rapid patient access

### Biosimilars

Will EU labelling guidelines  
cripple their market success?

### New Compass inside

Your guide to top life sciences  
events in the second half of 2016





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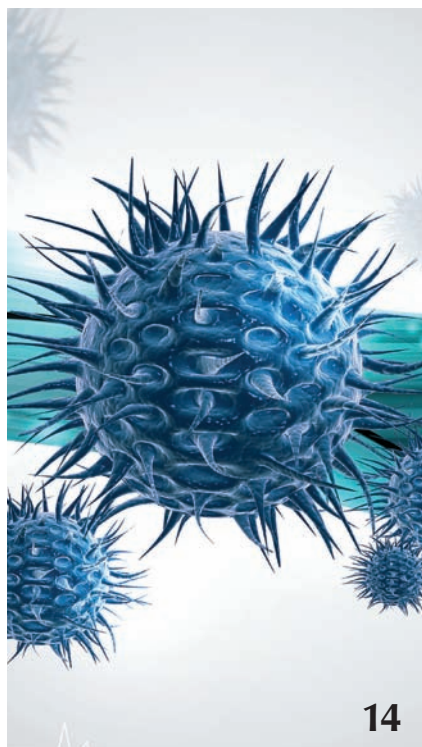
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FREE EXCERPT

## COVER STORY



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## Oncolytic viruses – Natural Born Killers

For over a century, doctors have known that some viruses halt or even reverse cancer. Because the effect was almost always temporary, however, development in the field has stagnated since the 1960s. Now interest in oncolytic viruses is surging, as progress in genetic engineering and cancer immunotherapy unlocks possible new approaches. Companies are inserting killer genes or ones that stimulate the immune system into tumour-targeting vectors. Could viruses be the key to curing a wide range of cancers?

## INSIGHT EUROPE

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## ECONOMY

## Fresh capital sought

2015 was a hallmark year for private equity in the life sciences in Europe. But even if the sector performed exceptionally well, there's plenty of room for improvement. The European Commission started the European Strategic Investment Fund about a year ago to kickstart the bloc's economy. Now more and more voices are clamouring for radical changes in venture financing.



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## BIOSIMILARS



74

## Will poor labelling thwart biosimilars?

Although the latest wave of biosimilar antibodies promises huge savings for payors, success stories from the branch are still few and far between. A lack of transparency has discouraged physicians from prescribing. Pharma and biotech stakeholders are calling on the EMA to change its labelling guidelines.

## EDITORIAL

## Open to innovation

In early June, the EMA accepted the first four therapies into its PRiority MEDicines scheme, an EU version of the FDA Breakthrough Therapy designation (p. 12). At the same time, the Agency is preparing a report on the outcome of a pilot project called 'Adaptive Pathways', which is designed to accelerate patient access to novel, life-saving medicines by granting staggered market authorisation (see p. 64). However, while the Agency pushes schemes that foster drug innovation, it may also be curbing the adoption of next-gen biosimilar antibodies. A recent survey commissioned by Europa-Bio and member companies found that the Agency's current biosimilar labelling rules are viewed critically by prescribing medical specialists in six EU markets (see p. 78).

Another pioneering field is highlighted in our cover story (p. 14). Eight months after the very first market approval for an oncolytic viral therapy against melanoma, the pipeline of viruses directed against tumours is growing. Agribiotech in contrast is facing stiff headwinds, both in terms of market access and regulation. For the first time in 20 years of commercial GMO cultivation, global acreage shrank in 2015. Meanwhile, the EU Commission is dragging its feet when it comes to making a decision on the regulatory status of crops created by new breeding technologies that prevent the use of transgenes.



Thomas  
Gabrielczyk  
Editor-in-Chief

## SPECIAL

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## FREE EXCERPT

# IMI calling

**FUNDING** The Innovative Medicines Initiative (IMI) has earmarked close to €60m to boost the R&D productivity of the European pharmaceutical industry. In its latest call for proposals, the public-private partnership of the EU Big pharma association EFPIA and the European Commission announced it will launch projects spanning from antimicrobial resistance flu, liver disease, rheumatic arthritis as well as medicines safety to data quality.

Fighting hospital-acquired infections with *Clostridium difficile* bacteria, which cause antibiotics-associated diarrhoea that can turn into a life-threatening pseudomembranous colitis, are the focus of the IMI's latest "antimicrobial resistance" project. It aims at improving the understanding of *Clostridium difficile* epidemiology, as well as treatment and prevention of the infection.

"Personalised" induction of immune tolerance is the headline of another project. Companies and researchers from academia and the biotech industry will try to restore the balance between proinflammatory T-effector (Teffs) and immune-dampening regulatory T cells (Tregs) in patients with the autoimmune disease rheumatic arthritis. In particular, they will search for ways to boost the activation of Tregs.

Identification of factors that improve the quality of preclinical drug safety data, particularly in neuroscience where animal models can hardly predict the effects in man, is the focus of an additional IMI project. The ultimate goal is to reduce the failure rate, cost and drug development times. Computer-based prediction of drug toxicity is subject to another project. Participants will create a huge database, which is aimed at correlating animal safety with human safety data.

Another topic is focused on finding biomarkers that identify patients with alcoholic fatty liver disease (NAFLD) whose disease will turn into the more serious condition non-alcoholic steatohepatitis.

Finally, IMI researchers will create a EU-wide platform to investigate and predict the efficacy of flu vaccines. ■

## Heard in Brussels

### EMA primed for action

**BRUSSELS** *We all know about the incredible amount of time it takes to bring a novel therapeutic to patients and the market, and the eye-watering cost associated with that process. It has broken many a person and richer and better than you or I.*

*The European Medicines Agency has introduced a new tool, called PRIME (like a Transformer™)*

*that can hopefully help applicants to accelerate approval, particularly those in advanced technology areas or where no treatment is currently available. As the world gets smaller, it is great to see that they nicked the idea off the Americans, as it reflects the Breakthrough Therapy programme over there which has been running at the Food and Drug Administration since 2012.*

*PRIME (PRiority Medicines) will offer selected programmes early and 'proactive' support with the aim to get registrations achieved after 150 days rather than the usual 210 – 60 very valuable days for both patients and patent holders. Not everybody can use this – you have to demonstrate potential to benefit patients with unmet medical needs based on early clinical data. However, once you have been picked, you get continuous support to build your marketing authorisation application, meeting with multi-disciplinary experts and receiving advice at key milestones including from Health Technology Assessment bodies.*

*This is good news for small companies, where cash is king and friends*



**CLAIRE SKENTELBERY**

Secretary General of the European Biotechnology Network

*with money are hard to come by. Acceptance into PRIME is a strong indicator of investment and partnering potential, helping de-risk highly novel potential therapeutics for larger companies which roll their eyes like a terrified horse at anything not shaped like a sugar cube. It's also good for Europe's translational research landscape, making it easier to*

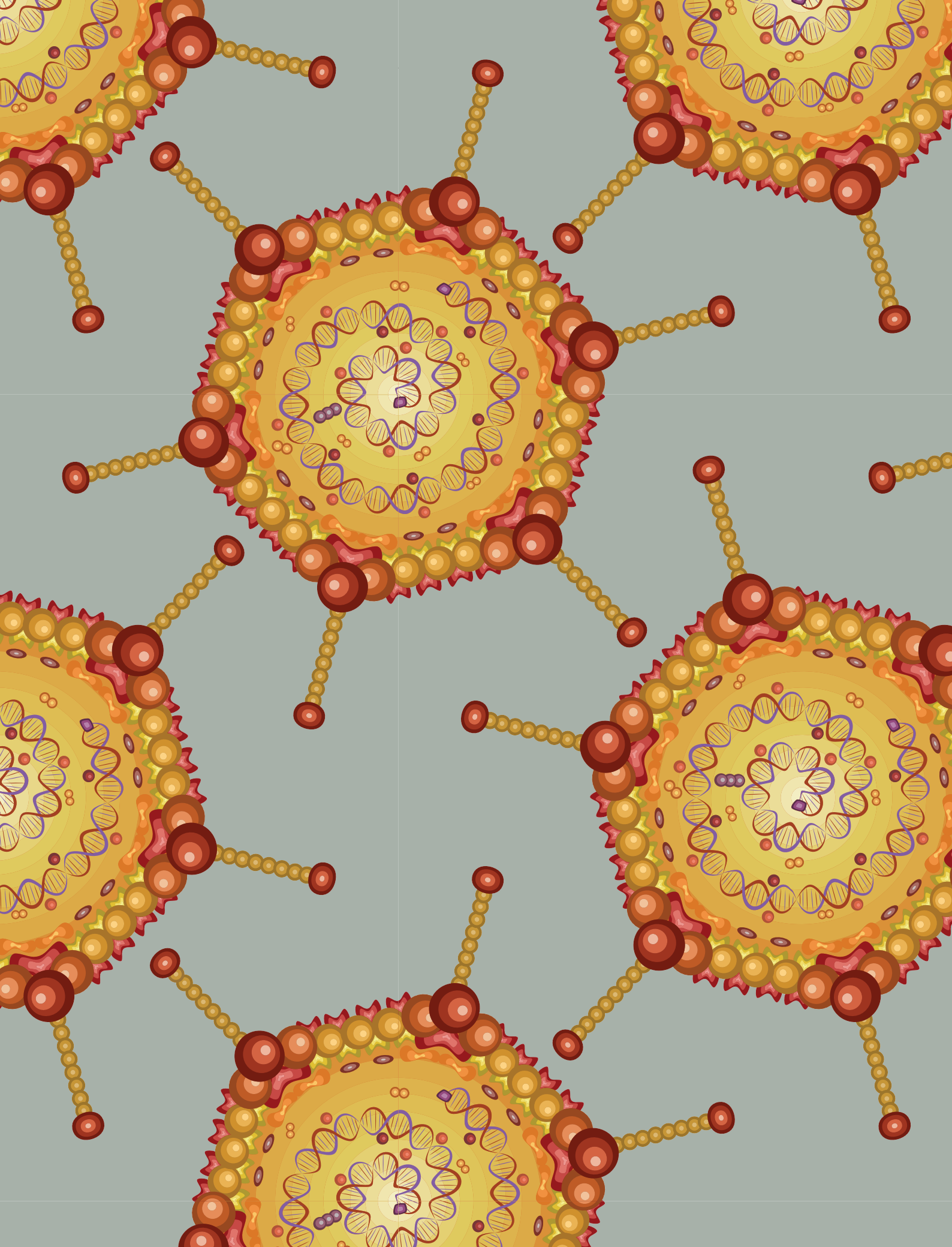
*take truly innovative ideas from the lab into development. Hopefully it will contribute to brains, money and momentum entering the pipeline.*

*And of course it is better news for patients – PRIME goes straight to those hard to reach spots and there are plenty of people there who won't get another chance of a novel medicine. To have something genuinely different become available when all you had hopes of was a reformulated 'something' is something that will sustain patients and their families in tough times.*

*With the close of recent calls from Horizon2020, which included advanced biomaterials for the treatment of neurodegenerative disorders, it looks like PRIME will be very useful. Medical research is combining the outcomes from breakthroughs in disease understanding with an increased ability to manipulate biology and merge it with many other technologies for the creation of medicines that boldly go where no medicines have gone before (always end with Star Trek if you can).*

*Make it so.* ■





# Natural Born Killers

**CANCER IMMUNOTHERAPY** Amgen's Imlygic was approved last year – a move that finally added oncolytic viruses (OVs) to the healthcare toolkit. Although the treatment's scope of application as a stand-alone therapy is limited, many are viewing the event as Ground Zero for an explosive new age in medicine. Evidence is mounting that the full potential of virotherapies can only be realised in combination with other immunotherapies, chemotherapies or small-molecule therapies. A number of other European drug developers have now jumped on Amgen's bandwagon.

The CMO of German drug developer Oryx Translational Medicine believes "oncolytic viruses combined with immune checkpoint inhibitors are the latest trend right now in cancer therapy." Michael Dahm says the combination has come about due to the fact, although the immune system can recognise and fight cancer early the process, most cancer cells are eventually shielded by an immunosuppressive setting. Hence, immunotherapies like immune checkpoint inhibition (CPI) can effectively strengthen the immune system, and help it regain the ability to destroy cancer cells. Researchers established that oncolytic viruses (OV) have the ability to tear

apart cancer cells long ago. Over the last few years though, data has begun to accumulate that they also potentially have immense immunotherapeutic value.

OVs basically come in two flavours: wild-type viruses whose anti-cancer response and attributes have been discovered more or less by chance, or genetically modified gene therapy hopefuls. The first tumour regressions after virus infections happened eons ago in healthcare terms – back in the late 19<sup>th</sup> century. The first local approvals of an OV came in 2004 (Latvia) for a wild-type enterovirus and 2005 (China) for a genetically modified adenovirus. Both treatments were developed outside the auspices of the Western science community. Dubbed rigvir for 'Riga virus', the

Latvian Picornaviridae family ECHO-7 virus has now also been approved in Georgia to treat melanoma, colorectal cancer and other tumours. The Chinese OV is used to treat head and neck cancer.

## Gem in the casket

Oryx is focusing on another wild-type virus. The H1 parvovirus (H-1PV) is a wild-type rat virus that infects and mediates lysis in cancer cells from various human tumours. Although the company has other clinical assets, Dahm calls H-1PV the "most precious gem in the Oryx casket ...

» Read the full story in the printed issue.

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# A burning need for financial growth

**FINANCING** Investments in Europe's life science sector were robust in 2015. The impressive performance of biotech stock markets over the last few years has engendered a renewed enthusiasm for plowing money into private companies, and rising numbers of US-based investors are also crossing the Atlantic. But even if the amount of cash flowing into the sector overall is climbing, some aspects of the business environment still desperately need improvement.

>> Read the full story in the printed issue.





# A crippling lack of information

**BIOSIMILARS** The US has opened the floodgates to cheaper versions of biologic medicines, and analysts predict that by 2020, biosimilar protein meds could seize a significant share of a projected €390bn market. That's good news for national health services and insurers, which stand to save billions in payouts. As expensive biologics begin to go off-patent, competitors with knockoffs are planning their onslaughts. But for biosimilars to have a future, both physicians and patients have to be sold on the idea – and many of them remain uninformed and unconvinced. The field is at a crucial juncture.

>> Read the full story in the printed issue.

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