



# European Biotechnology

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Life Sciences and  
Industry **Magazine**

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## Interview

AstraZeneca  
Executive VP and  
MedImmune Head  
Bahija Jallal out-  
lines strategy  
in immuno-  
oncology



## Biorefineries

A bird's-eye view of Europe's  
landscape for sustainable  
bio-based production

## Monoclonal antibody biosimilars

The next big thing to hit  
markets in the EU and US

## Biotech industry's IPO dilemma

Going public: should you  
launch here or across the pond?

## Biomanufacturing

Suppliers move to disarm  
complaints about leachables  
from single-use films

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# Waking the body's troops to fight cancer



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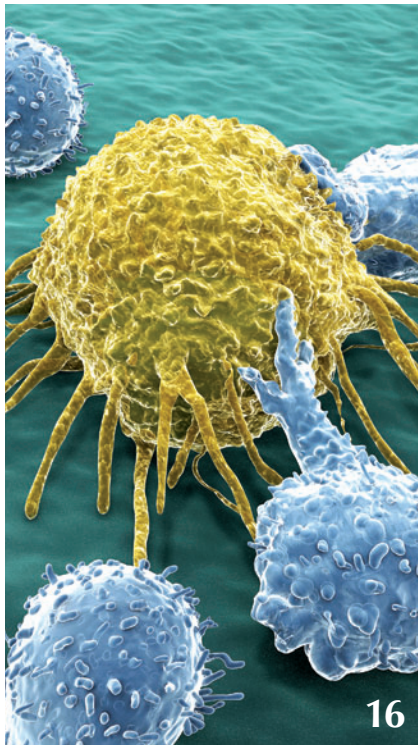
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## COVER STORY



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## Waking the body's troops to fight cancer

For more than three decades, drug developers have tried to understand how cancer tricks the immune system. Market approvals of the latest generation of immune checkpoint modulators are now raising hopes of a powerful weapon able to unmask tumour escape mechanisms. Because the new treatment seems to deliver lasting responses and a moderate side-effect profile, some physicians are calling it a new pillar of cancer therapy. Analysts see huge market potential for the technology in the next decade.

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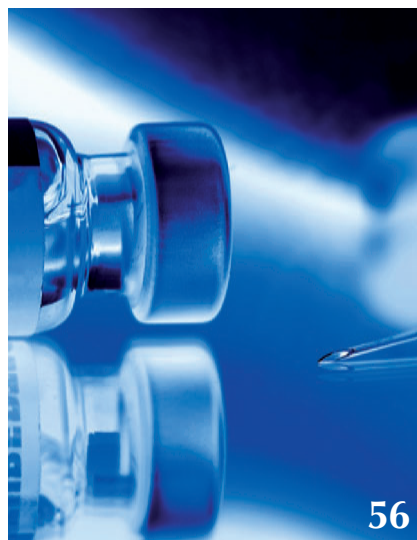
## Europe's bioleap into the future

Because Europe is a key player in the global race to set up the next generation of biorefineries, EUROBIOTECH has roughed out the current roadmap in the field. The kick-off of the EU's €3.7bn Bio-based Industry Joint Undertaking is a good starting point. But where does it need to go from there?



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## DRUG DEVELOPMENT



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## Will mAb biosimilars end the dry spell?

The first approval of a monoclonal antibody biosimilar in Europe and a wave of applications in the US have raised hopes for major market potential. EUROBIOTECH investigates current partnerships and pipeline projects.



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## EDITORIAL

## News that's just fast, or in-depth?

*The news business has changed, and dwindling revenues at daily papers reflect the growing use of almost real-time communication channels such as Twitter, or social networks. More and more people are increasingly shifting to the Internet as a source for instant information. We're not going to be left behind, though. In the best biological tradition, we've decided instead to adapt to the changing conditions. The European Biotechnology News has therefore switched phenotypes. We've found our new niche.*

*This first issue of the new quarterly European Biotechnology Magazine reflects the ongoing shift in information brokerage and consumption. In terms of layout and concept, we have completely relaunched our monthly news mag in an effort to marry tried and trusted columns and formats with new ones that provide our readers with added value. In the new Euro-Biotech magazine, you'll find relevant information with a longer half-life, with plenty of background reports on hot topics in the sector.*

*With large reports in this first new issue, and new sections devoted to Science & Tech and the activities of biotech associations, we begin to phase in more in-depth reporting.*

*Our sector is based on change. So let us know how you think we could make EuroBiotech even better!*

Thomas Gabrielczyk  
editor in chief





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**NIC ALEXAKIS**  
Head, Swiss Biotech Association

? Is it sufficient to fund Swiss basic research within Horizon 2020?

! Certainly not. It is crucial for Swiss biotechs, and for potential EU partners, to have a solution in place. If Swiss companies remain excluded, many projects that require their specific expertise will not take off.

## Swiss glimmer on Horizon

**EU FUNDING** Is it good news for Switzerland, or for the European Commission? After initially excluding Swiss researchers from the EU's giant Horizon 2020 funding programme following the controversial migrant referendum last February, the Commission granted Swiss researchers limited access to its €77bn pot until 2016.

From 15 September, outstanding basic researchers can gain access to Horizon's "Excellent Science" pillar. The compromise means they can apply for funding through the European Research Council, as well as the EU's Erasmus and Moonshot programmes. The solution prevents the untimely demise of the Commission's €1bn flagship "Human Brain Project", which is coordinated by Swiss researchers.

However, the other two Horizon 2020 pillars "Technology platforms" and "Societal Challenges", which are aimed at bringing lab inventions to market through industry collaboration, will remain closed to the Swiss. That's a blow to the country's SMEs like Novimmune, Gene Data or Polygene, which had attracted about €40m to carry out research collaborations with EU partners within FP7, the forerunner to Horizon 2020.

The Swiss Parliament, which had earmarked CHF4.4bn to finance the country's contribution to Horizon 2020, said that it will use parts of that budget to compensate excluded Swiss biotechs. Meanwhile, experts from the Swiss Biotech Association call on to continue EU negotiations in a bid to prevent further damage. ■

## GMO review

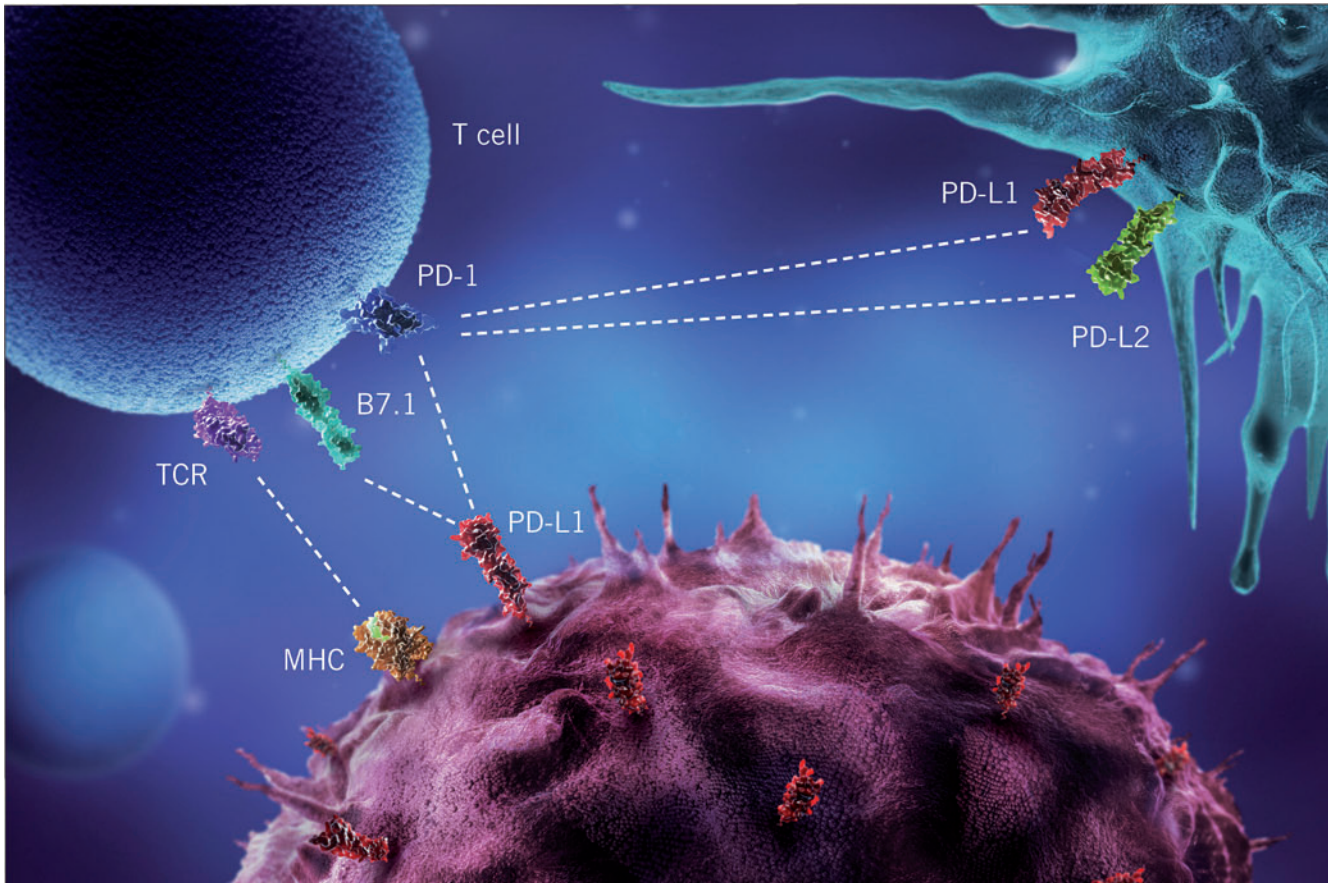
**EUROPEAN COMMISSION** GMO opponents are hopeful that Jean-Claude Juncker will see things their way. The President-elect of the European Commission, who "intend[s] to review the legislation applicable to the authorisation of genetically modified organisms," seems to support national bans on GMO acreage as well as on GMO import and processing. In September, he sent a tough message to the US, whose representatives told EUROBIOTECH that their focus is on securing exports for their farmers to Europe – but not forcing anyone to plant GMOs. According to Juncker, "it is simply not right that under the current rules, the Commission is legally forced to authorise new organisms for import and processing, even though a clear majority of Member States is against. The Commission should be in a position to give the majority view of democratically-elected governments at least the same weight as scientific advice [...]." Shortly after the statements, Juncker received a letter from 13 NGOs asking him to replace EU chief adviser Anne Glover, who has promoted GMO benefits in the past. ■



## BBI with absent industry leaders

**EU-INDUSTRY PARTNERSHIPS** In July, an unusual illustrious squad of EU officials and industry leaders in Brussels launched seven public-private partnerships under Horizon 2020: Commission President Barroso himself, two Vice-Presidents, Commissioners, representatives from the Council and Parliament. The new €3.7bn undertaking Bio-based Industries (BBI) was among the projects. Its aim is to trigger investments and to create a competitive market for bio-based products and materials "Made in Europe". Interestingly, in contrast to other big industries, almost no representatives from the European life sciences industry were present. EUROBIOTECH asked at the official BBI booth why? The answer: "We didn't invite them." ■

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# Waking the body's troops to fight cancer

**IMMUNO-ONCOLOGY** Drug developers are unravelling the signal pathways that cancer hijacks to trick the immune system, and market approvals for the latest generation of immune checkpoint modulators have raised hopes among oncologists, patients, companies and investors. Researchers have crafted a powerful new weapon that can cut off the tumour's immune escape routes, and physicians are calling the technology a new pillar of cancer therapy. Analyst estimates place its market potential at up to US\$35bn. The race to find the most effective combination therapies is on.

» Read the full story in the printed issues.

# A great bioleap forward

**NEXT-GENERATION BIOREFINERIES** Easy access to cheap feedstocks has encouraged countries with high agricultural output to develop extensive networks of first-generation biorefineries. Paradoxically, funding and technology from European companies often advances the bio-based revolution abroad more than it does at home. A €3.7bn public-private partnership (PPP) is about to change that.

There's no disputing the logic: "The more demonstration plants we have in Europe, the more industrial production will develop here," explains Dirk Carrez, Executive Director of the Bio-based Industries Consortium (BIC), the private partner in the new Bio-based Industries Joint Undertaking (BBI-JU) launched in July. While the industry is contributing the lion's share of BBI-JU funding (€2.7bn), the European Commission has also added another billion to the pot. The money is earmarked for research projects that will run until 2024. "Finally, we have a set budget and a stable long-term framework for several years," says Carrez. The scope of the programme isn't terrifically wide, but it could prove decisive, especially because it reaches out beyond already existing pilot facilities (see box on page 42): "We want to go a bit further in the innovation chain and also set up small-scale production plants." At demonstration plants, project beneficiaries can work on proof-of-concept for specific technology. "Right now, these kinds of projects are only realised in other parts of the world," complains Carrez.

The US has developed a bio-based economy around corn, while Brazil focuses on sugar cane. And Europe? "Here we have many different crops, which is an advantage because we are more flexible," explains Carrez. "But on the other hand, we have to develop different technologies to use all these different materials." That's one reason why the BIC chief is especially keen on sugar beet. Starting in 2017, the EU plans to end the current sugar quota system that allows countries and sugar com-

panies in a region to produce and market unlimited amounts of sugar, which leads to fluctuations in sugar prices driven by higher production and more export options. In fact, the European Commission's own impact study forecasts around a 45% drop in prices compared to 2012. "Sugar beet production is very efficient in some parts of the continent, such as northern France, Belgium and Germany," he says. Either by choice or forced by circumstance, big sugar companies like Südzucker, Nordzucker and Cargill have now joined the BIC.

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**"Let's take our time for a learning curve – one in which imperfect industries are allowed to develop."**

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But there are also those opposed, among them Manfred Kircher, who views the "focus on local raw materials" as "too restrictive." Kircher, cluster manager of German CLIB2021, is one of the driving forces behind the BIG-C initiative, which is seeking to concentrate and coordinate bio-based industry projects in Flanders (Belgium), North Rhine Westphalia (Germany) and the Netherlands. He argues that Europe has imported carbon sources for more than a century, and that the continent's export industry is now and will be dependent on imported raw material. For Kircher, it's not a question of "if", but "how" biomass is coming to Europe. "It's not like the oil industry," he insists. "There is still no cheap infrastructure for importing and distribut-

ing biomass." Crops and crop waste are too bulky. In the future, Kircher says, biomass needs to be transformed into an easily transferrable intermediate in its countries of origin, although he admits that it's "still not clear what intermediate will turn out most feasible."

Carrez counters by reminding the bioeconomy scene to keep things simple in the beginning. "We don't have to stretch to be as sustainable and cost-effective as possible from the outset. Let's take our time for a learning curve – one in which imperfect industries are allowed to develop. Under such a policy, we also need to use first-generation feedstocks like sugar." Second-generation (2G) feedstocks such as agricultural waste and its by-products have a big disadvantage: they require large amounts of energy to convert fibre into sugars. Because of demands made by the food industry, 2G feedstock-derived sugar will likely never be cheap enough to make it interesting for biofuels production. Like 1G sugar, it might one day be used for making speciality plastics or building blocks for chemicals, Carrez believes.

Europe already has a right to be proud of some achievements that will help provide a foundation for future endeavours. A year ago, for example, Beta Renewables – a joint venture between Italy's Gruppo Mossi & Ghisolfi (M&G), US investor TPG and Danish enzyme-maker Novozymes – inaugurated a plant in northern Italy that can produce 75 million litres of ethanol annually from rice and wheat straw. Beta Renewables claims its Proesa ...

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# Will mAb biosimilars end the dry spell?

**BIOSIMILARS** With its not even remotely surveyable range of market players, development projects and cooperations, the biosimilar field remains turbulent. Old clinical trials are dumped on an almost daily basis, while new ones spring up to take their place. In 2013, EMA approval of the first monoclonal antibody biosimilar (mAb) – a copy of J&J's arthritis drug Remicade (infliximab) from Korea's Celltrion – was a huge moment for the industry. Although a year down the road, we're all still waiting for the next mAb biosimilar to make it.

» Read the full story in the printed issues.



## Faked meds

**EFPIA** The European Federation of Pharmaceutical Industries and Associations (EFPIA) has established a new pan-European verification system with all supply-chain stakeholders in Europe aimed at recognising the (re-)introduction of stolen or counterfeit drugs into the European supply chain. Falsified medicines pose a serious threat to public health. Approximately 30 million doses of fake medicines were seized at EU borders in 2011 alone. According to the European pharma lobby group, the not-for-profit “European Stakeholder Model”, which has been developed since 2010 together with EU supply-chain stakeholders, can help to provide a solution. It records bar-coded serial numbers that correspond to every single package of manufacturer-produced medication. When repackaged, a link between the drug manufacturer's and a trader's serial number is saved. The system allows authorities to identify stolen drugs and relabelling with false new numbers. The approach was tested first in Sweden in partnership with Swedish retail pharmacy chain Apoteket AB and locally-based wholesalers Tamro and Oriola KD. The Securpharm project in Germany began supporting its phased implementation in 2013. ■

## IVD position

**EDMA** The European Diagnostic Manufacturers Association (EDMA) has published a position paper outlining its attitude to discussions on Annex XIII of the IVD Regulation proposed by the European Commission. The Dx-experts stress that it will be crucial to take IVD-specific terminology and issues into account before implementing rules for clinical evidence and post-market activities. They recommend using terminology from the Global Harmonization Task Force documents on clinical evidence for IVDs, and also urge more public clarity on the differences between IVDs and companion diagnostics. ■

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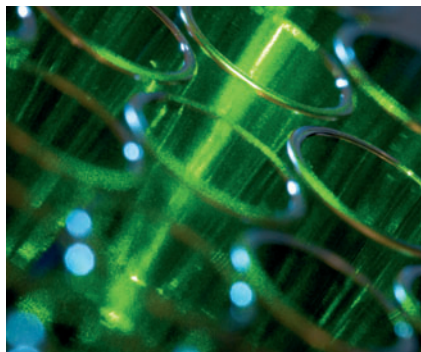
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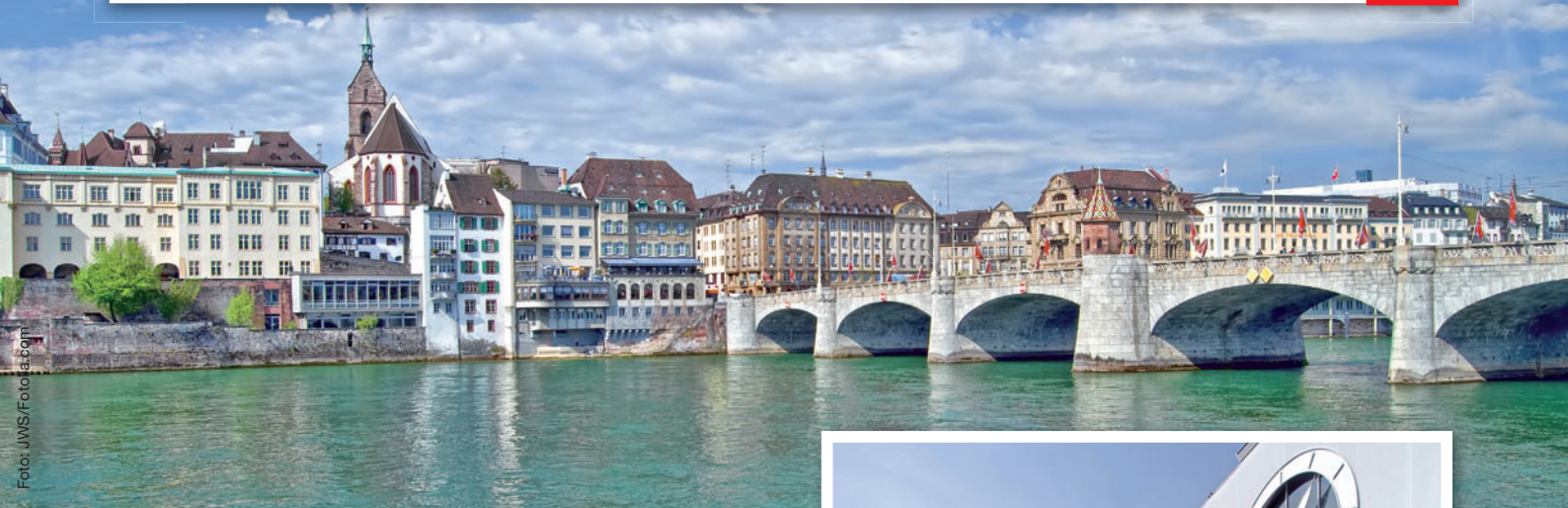
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