



European Biotechnology

ISSN 2364-2351 | A 60711 | BIOCOM

Life Sciences and
Industry **Magazine**

Winter Edition 2016 | Volume 15 | 20 €

Interview

Novartis litigation expert Jürgen Dressel on the impact of the EPO Early Certainty Initiative



Bioeconomy

Lodz Declaration lays down blueprint for EU bioeconomy strategy & action plan update

Drug development

3D bioprinted tissues are set to improve predictivity of preclinical disease models

Biopesticides

Next-generation antibodies expand beyond healthcare and into the world of agriculture

BioFairs Compass

Your unique guide to the leading life sciences events through the first half of 2017

Real World Data

FREE EXCERPT

Beyond clinical trials





**The place to be for life sciences
and healthcare industries**

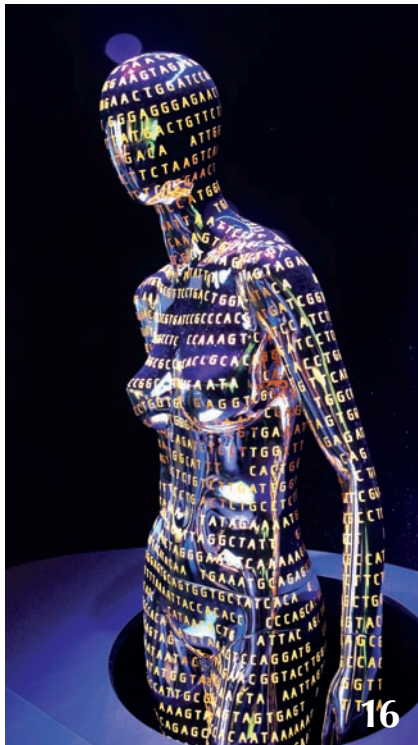
You are innovative.
You are growing rapidly.
You are well connected.
Then you are located in the
German capital region.

Not yet?
Learn what we have to offer!
www.healthcapital.de/en

Save the Date | Nov 6 – 8, 2017
Berlin – the place to be for BIO-Europe

FREE EXCERPT

COVER STORY



Real-world data set to transform medicine

Randomised controlled trials are the gold standard for determining the benefits and risks of new therapies. Yet, the data they bring comes with a downside, because generally, strict exclusion criteria for enrolment in such trials practically guarantees discrepancies with “real” patient populations, where multiple comorbidities or complicated pretreatment histories are common. Now technological advances are enabling study designs built on vast amounts of data from patients in “real world” therapeutic settings.

INSIGHT EUROPE

- 6 Lodz Declaration maps out new directions for the future orientation of the EU's bioeconomy
- 8 European Seeds Association applauds as Commission prohibits EU patents on essential biological processes
- 10 EU strengthens SME bio-base; Heard in Brussels
- 13 Interview: Jürgen Dressel, Novartis AG, Basel; Helmut Buschmann, AiCuris, Wuppertal; Andrea Sparwasser, Sphingotec, and Rainer Wessel, MIM Germany, on the impact of the EPO's Early Certainty Initiative
- 15 European Patent Office adopts obligatory fast examination; EU study shows health claims have little impact on consumers; Value creation by bioeconomy

ECONOMY

- 21 Update on clinical trials
- 24 EMA News
- 25 Analyst commentary
- 26 Euro Biotech Stocks
- 28 Belgian Fund+ closes at €125m; IP Flash
- 29 Start-up story: HiProMine SA, Robakowo, Poland

REGIONAL NEWS

- 56 Northern Europe: Sweden, Denmark, Finland, and Norway
- 58 Western Europe: France, Belgium, The Netherlands, and the UK
- 60 Central Europe: Germany, Switzerland, and Austria
- 62 Southern Europe: Italy, Spain, and Croatia
- 64 Eastern Europe: Hungary, Poland, Czech Republic, and Lithuania

SCIENCE & TECHNOLOGY

- 70 CROs: Checklist for instantaneous drug development
- 71 Hookworm protein soothes inflammation; Myocardial patch helps heal heart infarction scars
- 72 Putting the brakes on autoimmunity

SERVICE

- 73 News from partner associations: SBA, BIO Deutschland, DIA, EBN and EDMA
- 79 Biopeople
- 80 Events
- 81 Company index/Product
- 82 Encore

DRUG DEVELOPMENT

Drug screening in 3D tissues

For years, pharma companies have sought to improve R&D productivity but have failed due to rogue disease models. Human tissues obtained by stem cell differentiation or 3D bioprinting are now paving the way towards improved prediction of preclinical drug toxicity and efficacy. Yet, many challenges remain.



30

AGRICULTURE



66

Biological bugkillers

Antibodies have been a game-changer in a number of different medical fields, particularly oncology and autoimmune diseases. Yet, biologics also have a lot of promise in the area of crop protection, as they can be selected to attack pests very specifically. More and more big companies are now entering a fast-growing field that analysts predict will soon be worth billions.

EDITORIAL

Green pesticides

The European Food Safety Agency recently warned that 6.5% of food imports from third countries contain pesticide residues that exceed EU maximum permitted levels. However, there might be a way to avoid toxicity, carcinogenicity, pathogen resurgence and the damage to biodiversity caused by current chemical weed and pest killers. In this edition, European Biotechnology editor Martin Laqua discovered that agriculture giants like Germany's BASF are pushing to develop next-generation biopesticides, which experts believe could seize a 10% share of the crop protection market by 2023.

In September, the largest chemistry company on the globe entered into a collaboration with French Plant Advanced Technologies to select the best candidates from "plant milking", a technique that non-destructively harvests promising new compounds from the roots of plants. The new approach could appease opponents of GMO technologies, as the new pesticides are derived from nature.

Those opponents have no objections to the direct application of Bt toxin in organic farming – as long as it's only sprayed and not expressed by genetically modified plants. Let's hope biopesticides won't be prejudged in the same way.



Thomas Gabrielczyk
Editor-in-Chief



SPECIAL

EU Event Compass

- 37 Intro: mark your calendar
- 38 EBD Biotech Showcase, San Francisco
- 40 Berlin Conference on Life Sciences
- 42 Pharmabiotics 2017, Paris
- 44 BIO-Europe Spring, Barcelona
- 46 Annual Congress on Pharma Med
- 48 DIA Bioventure Day, Glasgow
- 50 Swiss Biotech Day, Basel
- 52 10th International Conference on Bio-based Materials, Cologne
- 54 9th International Meeting of the Stem Cell Network NRW, Münster

FREE EXCERPT

Strengthening the bio-base

BIOECONOMY The European Commission has launched a follow-up to the successful Bio Base NWE project running from 2013-2015. In October, Brussels kicked off the three-year INTERREG NWE project "BioBase4SME," designed to push the development of the bio-based economy in North West Europe (www.nweurope.eu/BioBase4SME). The €5.83m project is aimed at helping biotech SMEs to overcome technological barriers and the financial valley of death on their path to commercialising bio-based inventions.

Managed by leading bioeconomy clusters in Belgium, France, Germany, Ireland, the Netherlands, and the UK, BioBase4SME offers training, innovation biocamps, workshops, and innovation coupons worth up to €100,000 each. These coupons can be used for technological assistance, such as scale-up to pilot scale, Life-Cycle Assessment (LCA), techno-economic evaluation, market research, feedstock analysis, social acceptance, and business planning support, or a combination thereof. The BioBase4SME partnership includes eight organisations from six different countries.

"We expect to bring at least 20 promising innovations closer to the market," said BioBase4SME Manager Lieve Hoflack, "and provide training to about 200 entrepreneurs active in the bio-based economy. Other main outputs could be a strong, interregional network to guide entrepreneurs towards successful innovation and improved regional support for the bio-based economy, in terms of innovation and investment climate, regulatory framework, and public approval," he added.

Outcomes from the previous Bio Base NWE innovation coupon scheme seem to prove him right: It instigated a leverage effect of €71m of investments and created 320 new jobs in the biobased economy. ■

Heard in Brussels

And the world turns

BRUSSELS *Well, that was a weight off my chest, better out than in, as they say. After Brexit, at least the world will be pulled back into its axis with the election of America's first woman president and ... wait a minute, what are you saying? No, that can't be right ... he won? Really? REALLY?*

The news, as I write this, rounds off a bewildering year. The editor asked me to write another feisty piece, as apparently you unwashed mob out there quite like slightly naughty writing. And the results of the US election provide a perfect opportunity. However, I find myself unable to laugh or be angry about a farcical, ugly process, with a farcical, ugly result. Maybe it is because I wasn't a voter so I don't feel personally offended.

Bad trend

So, what do I feel? Sitting in the centre of the EU, a group of 27 (yes, I know the UK hasn't left yet, but they got their coat and are standing by the door) countries that, for better or worse, richer or poorer, work together because that will bring you a better, more secure, long-term future.

I feel profoundly sad. Events this year appear to have made it acceptable to actively dislike and attack people because of their race, gender, intellectual capability, and any other factor that makes you think they are plotting to take food out of your mouth. Just as Brexit has seen a sustained increase in race-related violence in the UK, in



CLAIRE SKENTELBERY
Secretary General of the European Biotechnology Network

the US, where people have been described as rapists and murderers for being Mexican, I wonder how many people will lose their lives for the crime of not fitting a rather narrow spectrum of acceptability.

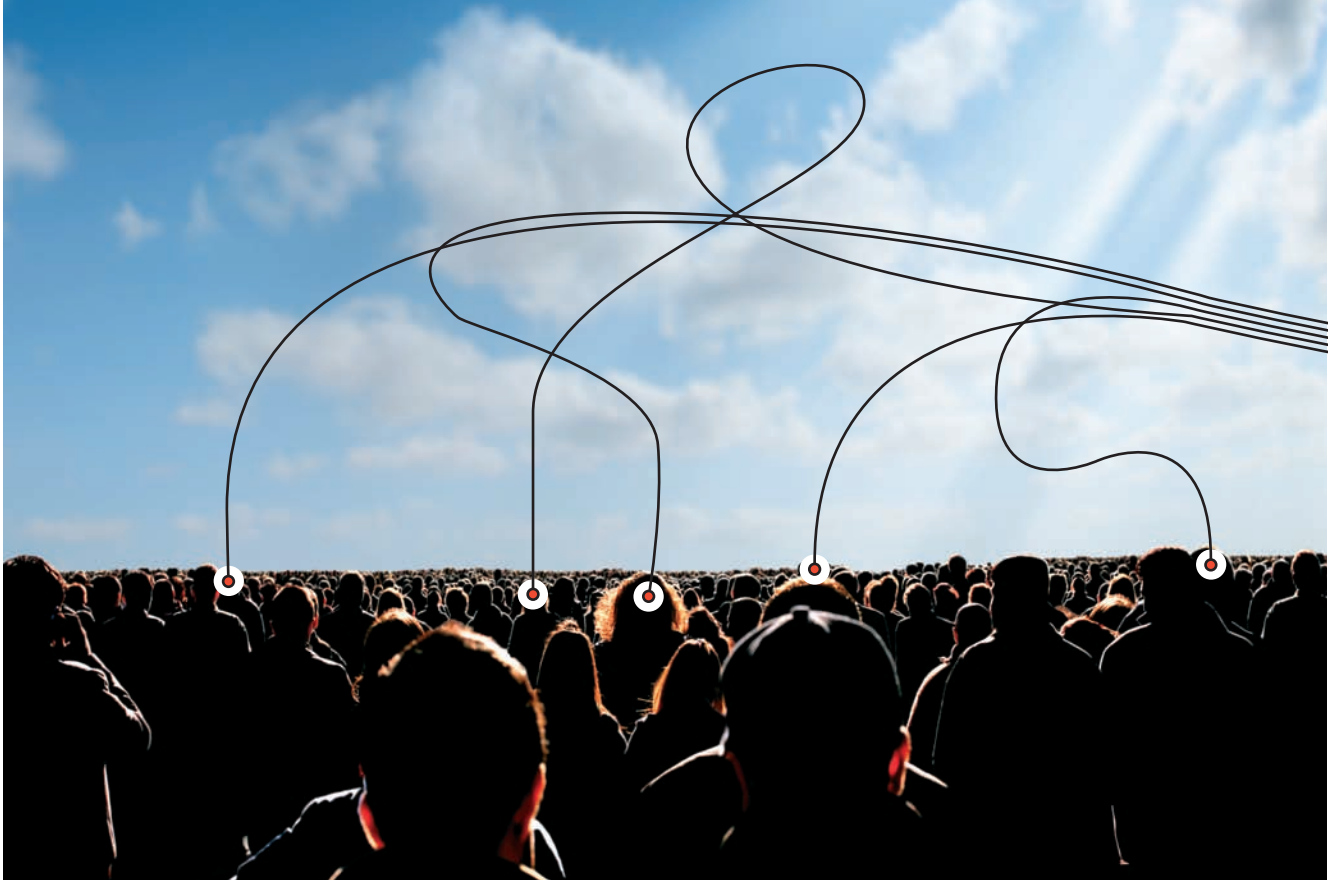
It makes me even more glad that I am part of the European Union. Whatever its challenges, and there are many, it has fixed a target of things being better for its cit-

izens, and that does not mean a tiny percentage, but all of them. Hence, better air, water, employment rights, unemployment rights etc., are applied for all people. When countries as diverse as Hungary, Greece, Germany, and France recognise this and pull (often reluctantly) together – that has to tell you something about the "rightness" of the long-term goal.

The US now has a profoundly anti-science government. Climate change, vaccine-linked autism, evolution ... it is hard to even know where to start. These are all evidence-based positions accepted by the global science community, and they could be torn up if the extreme statements from the election trail are implemented. Science policy from Sarah Palin or Ben Carson? This will not just impact the US, as the EU and US have been working to align science delivery, and the danger is that this could be undone, to the cost of patients and healthcare. One can only hope that, in the bonfire of sanity that seems about to ignite, that they don't set fire to scientific structures and relationships that have been so carefully constructed.

Signing off from Brussels. ■

FREE EXCERPT



Out of the trial and into the real world

REDEFINING EVIDENCE Only a small fraction of carefully selected patients are allowed to enroll in randomised controlled trials involving new compounds – the gold standard of drug assessment. But trying to acquire the most significant efficacy and safety results for a new drug is one goal, treating patients every day in hospitals or practices with it is something else entirely. Discrepancies are inevitable. Now “real-world data” that’s been gathered in large observational studies is attempting to close the gap between experimental, artificial study settings and clinical realities.

» Read the full story in the printed issue.

FREE EXCERPT



Screening drugs in multiple dimensions

3D BIOPRINTING/ORGANOIDS 90% of all preclinical drug candidates fail to make the grade. Now novel methods that employ miniaturised organs could help overcome this healthcare hurdle. Researchers and CROs are testing a range of models – whether grown from stem cells or spit out by 3D bioprinters – to identify toxicities, simulate cancer development and identify responders to expensive therapies. The field of 3D microtissue-based screening is just a decade old, but it clearly is soon going to play a key role when it comes to improving productivity in drug development.

» Read the full story in the printed issue.

FREE EXCERPT



Of strawberries and antibodies

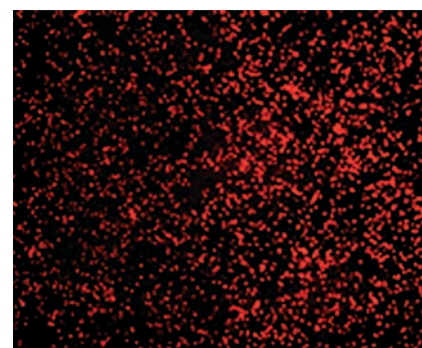
BIOPESTICIDES Over the last decade, therapeutic antibodies have fundamentally changed approaches in different areas of medicine, providing the impetus for a big leap forward in the treatment of cancers and autoimmune diseases. But could they also soon have a lasting impact on agriculture? Some pioneers predict that – in the near future – peptides, proteins and RNA will be driving markets in the fast-growing biopesticide and biostimulant sectors.

>> Read the full story in the printed issue.

4-Antibody AG (CH)	64
AbbVie Deutschland GmbH & Co. KG	23
AbbVie Inc. (USA)	21
Ablynx BV (BE)	23, 67
Aelix Therapeutics (ES)	63
AgroSavie BV (BE)	67
AiCuris GmbH & Co KG (DE)	12
ALPLA (F)	58
Amgen Inc. (USA)	59
Apeiron Biologics AG (AT)	60
Apitope NV (UK/B)	21, 22, 59
ARCH Venture Partners (USA)	59
arGEN-X B.V. (NL)	22
Asarina Pharma AB (SE)	59
Astellas Pharma Europe B.V. (NL)	31, 60
AstraZeneca AB (S/UK)	21, 59
ATS Beteiligungsverwaltung (DE)	60
Aura Biosciences (USA)	63
AVA Biochem BSL AG (CH)	58
Avantium NV (NL)	58
BASF AG (DE)	58, 67, 68, 69
Bavarian Nordic A/S (DK)	25
Bayer AG (DE)	67
Berlin-Chemie AG (DE)	63
Bio-On S.p.a. (IT)	62
Biocartis Group NV (BE)	59
BIOCOMAG (DE)	14, 33, 61, CP3
BioEcho Life Sciences GmbH (DE)	61
BioMarin Europe Ltd. (UK)	25
Biondistry Park Silvano Fumero S.p.a. (IT)	33
BioPhausia AB (SE)	56
Biovest (BE)	28
Boehmert & Boehmert (DE)	28
Boehringer Ingelheim (DE)	21, 23
Bristol Myers Squibb (USA)	31
CANDOR Bioscience GmbH (DE)	13
Capricorn (BE)	28
Cassiopea SPA (IT)	22
Cellbricks GmbH (DE)	31
Collectis (F)	58
Cellink (SE)	56
Celon Pharma Ltd. (PL)	64
Chemopolis Oy (FI)	57
Cinfa Biotech (ES)	23
Clovis Oncology Ltd. (UK)	25
Cobra Bio (UK)	57
Coca-Cola (USA)	58
Corbion Purac (NL)	58
Cosmo Pharmaceuticals (IT)	22
CRISPR Therapeutics (CH/USA)	61
Curevac GmbH (DE)	61
Cytune Pharma SAS (F)	64
Daiichi Sankyo (JP)	22
Danone (F)	58
DGPharMed (DE)	47
DIA EMEA (CH)	49
Dilaforette Holding AB (SE)	56
Dong-A Socio Holding (KR)	65
DS Biopharma (IRL)	22
DuPont (USA)	58
Dust Biosolutions (DE)	60
Eastman Kodak (USA)	58
EBD Group (CH)	39, 45
Editas Medicine (USA)	61
Enterprise Therapeutics (UK)	79
EpimAb Biotherapeutics (Shanghai)	58
Eppendorf AG - Bioprocess Center Europe (DE)	9
Ergomed plc (UK)	59
EtherNA immunotherapies NV (BE)	28
EuropaBio /European Biotech Week (BE)	Supplement
European Biotechnology Network (BE)	36
EUSA Pharma (UK)	60
Evotec AG (DE)	59
Faron Pharmaceuticals Ltd. (FI)	14
Five Prime Therapeutics Inc. (USA)	25
Forum Corp. (FI)	57
Fund+ (BE)	28
Galapagos NV (BE)	23, 25
Ganymed GmbH (DE)	60
Gedeon Richter Ltd. (HUN)	65
Genentech Inc. (USA)	72
Genmab A/S (DK)	22, 25
Genomics Medicine Ireland	59
GIMV (BE)	28
GlaxoSmithKline (UK)	79
Google Inc. (USA)	59
GW Pharma (UK)	25
Heidelberg Pharma AG (DE)	57
HiProMine SA (PL)	29
Horizon Discovery Ltd. (UK)	25
Hybrigenics S.A. (F)	22
IKEA Group (SE)	56
Immunovia AB (SE)	25
Innate Pharma SAS (F)	26
Inotrem SA (F)	22
Ireland Strategic Investment Fund	59
Iteos Therapeutics SA (BE)	28
Janssen Research & Dev. (BE)	21
Johnson & Johnson (USA)	22
Karo Pharma (SE)	56
Kompetenznetzwerk Stammzellforschung NRW (DE)	55
Kymab Ltd. (UK)	58
LRM (BE)	28
Mabion S.A. (PL)	65
Marrone Bio Innovations (USA)	68
Mastercell SA (BE)	28
Medifundo GmbH & Co.KG (DE)	61
Medivir AB (SE)	56
Meiji Seika Pharma (JP)	65
Menarini Biotech S.r.l. (IT)	63
Merck & Co. (USA)	31
Merck KGaA (DE)	21, 22, 23, 59, 68
Meusinvest (BE)	28
MIG Verwaltungs AG (DE)	60
MIM Germany	12
Minoryx Therapeutics S.L. (ES)	63
Modus Therapeutics Holding (SE)	56
Monsanto (USA)	67, 68
MorphoSys AG (DE)	21, 23
Mylan (NL)	65
NBE Therapeutics AG (CH)	64
Neste Jacobs Oy (FI)	56
NeuroVive Pharmaceutical AB (SE)	22
Neuway Pharma GmbH (DE)	57
Nimbus Therapeutics (USA)	72
Nordic Nanovector AS (N)	57
nova-Institut GmbH (DE)	53
Novadip SA (BE)	28
Novamont S.p.A. (IT)	63
Novartis AG (CH)	12, 21, 31
Novo Nordisk A/S (DK)	25, 57, 79
Novozymes A/S (DK)	68
Ocello (NL)	31
Ogeda SA (BE)	28
OPIS s.r.l. (IT)	23
Organovo (USA)	31
Oryzon Genetics S.A. (ES)	63
Oxford Nanopore Technologies Ltd. (UK)	82
PCI Pharma Services (UK)	11
Pfizer (USA)	23
Pfizer Centre One (USA)	CP4
Pharmabiotics Global 2017 PRI (UK)	43
Plant Genetic Systems N.V. (BE)	68
PledPharma (SE)	57
PMV (BE)	28
Polaris Partners (IRL)	59
polpharma biologics (PL)	7
Poxel SA (F)	25
PPF Group (CZ)	64
Prexton Therapeutics SA (CH)	63
Promethera Biosciences (BE)	28
Promocell GmbH (DE)	81
Reviral Ltd (UK)	23
Roche AG (CH)	22, 31, 59, 72
Sanifit (ES)	63
Sanofi SA (F)	59
Santhera Pharmaceuticals (CH)	23
Sotio a.s. (CZ)	64
Spark Therapeutics (USA)	25
SphingoTec GmbH (DE)	12
Sun Pharmaceuticals Ltd (IND)	21
Swiss Biotech Association (CH)	51
Symcel (SE)	57
Symphogen A/S (DK)	79
Syngenta AG (CH)	67
Symvina (NL)	58
Taaleri Kiertotalous Ky (FI)	57
Takeda Pharmaceuticals (JP)	18
Tika Diagnostics (UK)	57
Twincore GmbH (DE)	71
UCB SA (BE)	21
Valneva (F)	25
Verily Life Sciences (USA)	59
Vertex Pharmaceuticals (Europe) Ltd. (UK)	25, 31
Vesalius Biocapital Partners S.a.r. (LU)	28
Vetter Pharma-Fertigung GmbH & Co.KG (DE)	21, 70
Wilex AG (DE)	57
Xellia Pharmaceuticals ApS (DK)	62
Ysios Capital Partners (ES)	63
ZAB Brandenburg Ec. Dev. Board (DE)	CP2

Fast & Sensitive

PROMOCELL PromoKine's EdU-based Cell Proliferation Kits III provide a superior alternative to classical BrdU and radioactive [3H]thymidine assays and are each optimised for fluorescence microscopy, flow cytometry, as well as high-throughput quantification using a fluorescence plate reader. EdU is a nucleoside analogue to thymidine and is incorporated into DNA during active



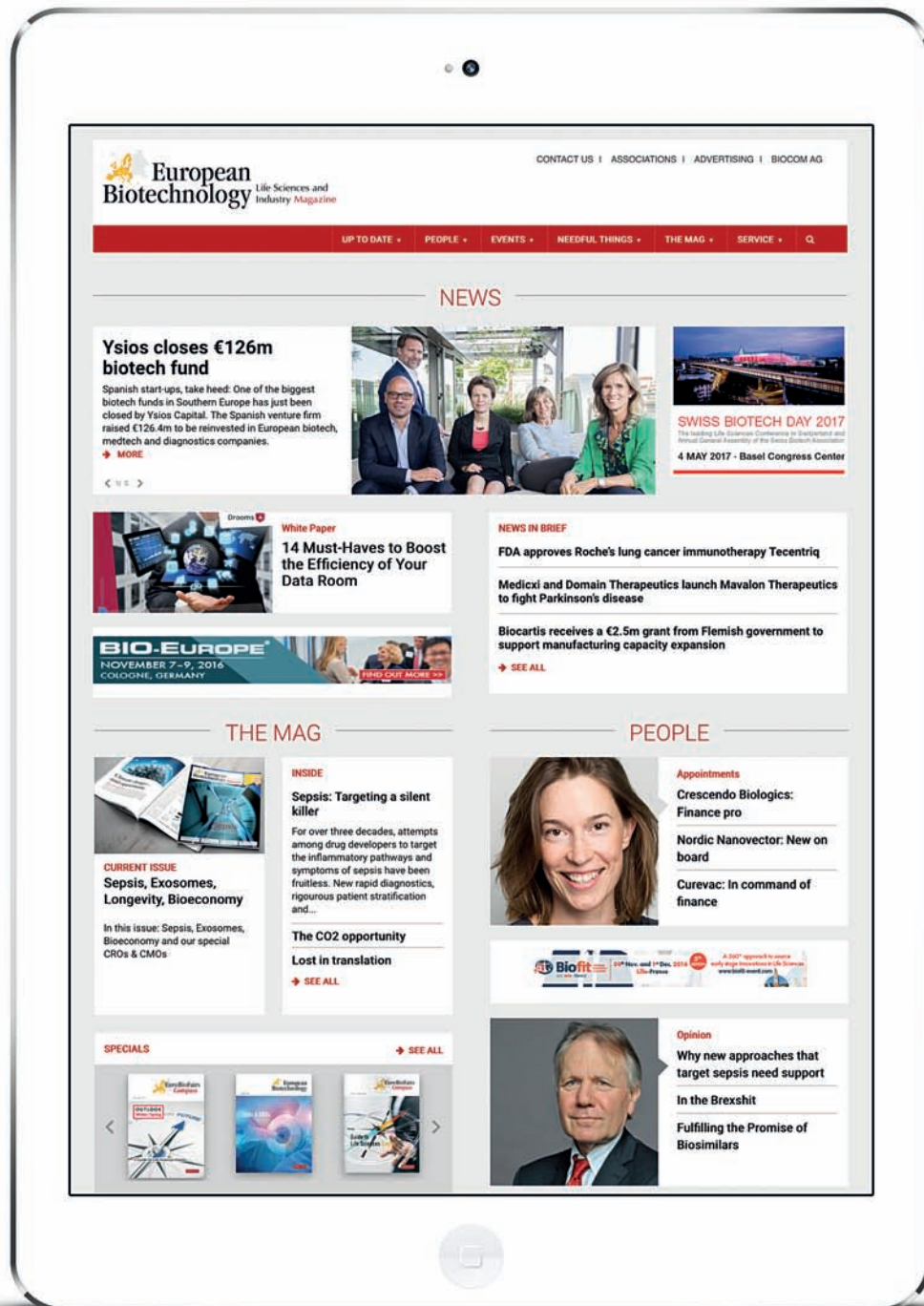
DNA synthesis. In contrast to the classical BrdU assays, Promocell's EdU-based cell proliferation assays are not antibody-based and, therefore, do not require harsh, sample-compromising DNA denaturation for detection of the incorporated EdU.

Instead, the assays utilise the fast and simple click chemistry for easily coupling fluorophores to the incorporated EdU, allowing a more rapid and sensitive detection and quantification in a variety of fluorescent readouts. The simple click chemistry detection procedure is gentle on the cell samples, completed within only 30 minutes, and compatible with multiplexing for content- and context-rich results. Compared to the BrdU assay, the streamlined detection protocol of the EdU-based assay reduces the total number of steps and significantly decreases the total amount of time.

CONTACT

PromoCell GmbH
 Sickingenstrasse 63/65
 69126 Heidelberg, Germany
www.promokine.info
info@promokine.info

Europe's No. 1*



european-biotechnology.com

* For almost two decades, European Biotechnology has been the first and foremost information platform reporting on the life sciences in Europe. european-biotechnology.com is ranked No.1 on Google.com, search terms biotechnology+europe.

Bringing together the best of

ONE **2** ONE™

Pfizer CENTRESOURCE



CentreOne

Contract Manufacturing



When it's
YOUR
compound,
every step
matters.

www.pfizercentreone.com

API

DRUG PRODUCT