IN brief

First mass spectrometry diagnostic approved in US

The US Food and Drug Administration in August approved its first mass spectrometry (MS) diagnostic for clinical microbiology use. The VITEK MS, manufactured by the French multinational bioMérieux, based in Marcy-l'Etoile, uses matrix-assisted laser desorption/ionization time-of-flight MS to analyze the proteins of microorganisms and compare them to its vast database of signature profiles. In conventional microbial identification, microbes isolated from patients are subjected to more expensive and slower biochemical and molecular assays before clinicians can act on the information. Given a pure culture of a bacterium or fungus, the VITEK MS can pinpoint its identity at the species level in minutes, with the ability to perform nearly 200 tests at once. The platform is already approved for use in Europe and other countries, but was finally cleared in the US through the *de novo* pathway, which is used for low-risk devices of a new type that would not warrant premarket approval. A very similar rival platform, the Biotyper from Billerica, Massachusetts-based Bruker, is right behind bioMérieux, with a 510(k) application pending. According to Estée Torok of Addenbrooke's Hospital, Cambridge, UK, who uses the Bruker Biotyper, the technology has revolutionized microbe identification in the diagnostic laboratory. At a fraction of the price per identification of older methodology and producing comparable results, MS-based devices like VITEK and Biotyper, Torok predicts, may one day supplant the traditional identification workflow in most clinical settings.

Jennifer Rohn

IN their words

"In order to hit sales at rival companies and push the company's own products, bribes and special payments of all sorts were extremely common at the company. The level of the problem was just

as bad as at GlaxoSmithKline." Wei Wang (pseudonym) former senior manager at Eli Lilly, which is alleged to have spent over \$30 million in bribes to Chinese physicians. (*Reuters*, 22 August 2013)

"It's that the provision of physician notification creates a psychological barrier to prescribing biosimilars." Tom Bone, legislative advocate for CVS Caremark pharmacies commenting on the possible impact of a biosimilar law under consideration by the California legislature. (*California HealthLine*, 22 August 2013)

Scripps boosts research coffers by selling reagents to Sigma-Aldrich

Six high-profile laboratories at The Scripps Research Institute have entered an alliance with Sigma-Aldrich that is the first of its kind for a chemical reagent supplier. Under the agreement announced in July, Sigma-Aldrich obtains an exclusive license to research reagents coming out of research laboratories led by Phil Baran, Jin-Quan Yu, Benjamin Cravatt, Carlos Barbas, Phillip Dawson and Barry Sharpless. The St. Louis-based Sigma-Aldrich will offer the Scripps researchers' cutting-edge drug discovery tools to its customers immediately after publication, in exchange for research support to Scripps. The transaction, which improves the coordination

between reagent discovery and commercialization, benefits the wider scientific community by enabling rapid access to the latest reagents. It also bolsters Scripps' research funding, an option that other academic institutions may find appealing in light of the new realities of research funding in the US.

Cutbacks in government grant support have made academic institutions like Scripps more flexible in considering commercial arrangements. The pharma-biotech industry has new balance-sheet concerns of its own and is turning to academia in new, more targeted ways as it seeks to externalize its R&D. Thus, although La Jolla, California-based Scripps has a history of signing blanket 'first-rights' agreements with large drug companies, those firms are no longer offering such massive, open-ended research support.

Within this alliance, which has the structure and feel of an alliance between a pharmaceutical company and a not for profit, the Scripps teams will devise reagents and building blocks that improve the processes of medicinal chemistry and chemical biology, such as catalysts and probes and peptide-type chemistries. The Yu laboratory, for example, is focused on carbon-hydrogen bond-forming activation. Such bond creation is useful in improving catalytic reactions that parallel enzymatic transformations in terms of their reactivity and selectivity, and so is of interest to researchers building compound-screening libraries.

Sigma-Aldrich had previously established one-time relationships for specific reagents with the Sharpless laboratory (for reagents useful in performing 'click' chemistry, a platform that uses a set of reliable, selective reactions for the rapid synthesis of new compounds) and with Baran's group (to commercialize a toolkit

of zinc salts including difluoromethanesulfonate, used to insert fluorine atoms directly into various organic substrates). But the multilaboratory scope of the new arrangement, which anticipates Sigma-Aldrich getting exclusive rights to classes of reagents not yet developed as well as those almost ready to roll out, is what makes this deal

the first agreement of this sort. "I don't think anybody has tapped a reagent company or allowed a reagent company to tap them in quite this way," says Scott Forrest, vice president of business development at Scripps. It's also the first time Sigma-Aldrich has made upfront investments for external reagent development.

Speeding time to market was a crucial consideration on both sides. There's usually a time delay between a publication showing the use of a reagent and its commercial availability of up to 12 months. But for the Scripps laboratories, products will be available at the time of publication.

"We believe that will help accelerate research into new areas of research," says Amanda Halford, vice president, academic research, at Sigma-Aldrich. The time of publication is when the most interest and awareness is generated. "It's the peak of demand for reagents," she says.

Having small quantities of reagents ready to go together with the publication references will also allow Sigma-Aldrich to get an early read on how commercially viable a reagent is and to jointly troubleshoot any issues of process scale up, so they can commercialize the products seamlessly. Rapid access may also pave the way for quicker evaluation of reagents from other laboratories that could become part of the drug development process, ranging from target identification through to medical chemistry areas to clinical. And by networking with the

The Scripps Research Institute, home to Nobel prizewinners and pioneering scientists, is a nonprofit research institution whose philosophy is the pursuit of basic knowledge in life sciences for its application in medicine.