

IN brief

Epigenomic colon cancer kit

A blood-based epigenetic test for colon cancer has been launched in Europe, a diagnostic tool that could boost screening compliance and lead to significant cost savings. The Epi proColon test from Berlin-based Epigenomics detects methylation patterns in cell-free DNA in blood plasma. The assay converts all nonmethylated cytosine residues into thymine followed by PCR, which amplifies a region of the gene septin 9—specifically methylated in colon cancer—for quantitative assessment. The company hopes that its noninvasive assay is easier to use than stool-based fecal occult blood tests (FOBTs), currently the mainstay for early detection, but it does not see it replacing colonoscopy for a definitive diagnosis. The test is the first epigenetic diagnostic to be sold as a kit to laboratories; other epigenetic-based tests on the market, including cancer diagnostics and a test to predict how brain-tumor patients will respond to treatment, are run in the diagnostics makers' laboratories. The Epi proColon test, which consistently identifies 70% of cancers, could potentially lead to significant savings for healthcare providers by reducing screening costs and the cost of treating advanced cancers. But Durado Brooks, director of prostate and colorectal cancers at the American Cancer Society in Atlanta, has his concerns. "If it has to be done on a population basis once a year, frankly there's going to be no cost savings whatsoever," he said, citing cheaper annual FOBT and decadal colonoscopy costs.

Asher Mullard

GSK adopts antisense

GlaxoSmithKline (GSK)'s recent collaboration with Prosensa on therapeutics for Duchenne muscular dystrophy (DMD) is another sign that large pharma is willing to focus on niche markets. DMD is a childhood neuromuscular disease caused by a mutation in the dystrophin gene, the normal product of which is necessary for proper muscle formation. It affects 1 in 3,500 newborn boys, causing muscle weakness that often leads to respiratory or cardiac failure. Under the alliance, announced in October, GSK licenses Leiden, The Netherlands-based Prosensa's PRO051, an antisense RNA oligonucleotide that skips exon 51 of the gene dystrophin, allowing for production of a functional protein. The compound is scheduled to enter phase 3 trials early next year. The London-based pharma is paying \$25 million upfront for the program, which also includes options on three other compounds targeting different exons (the mutation addressed by PRO051 is responsible for only 13% of DMD cases), and will fund clinical development. The deal "fits squarely in with our current strategy of diversifying into other broader disease areas, accepting that it won't have anywhere near the return of a blockbuster," says Shelagh Wilson, vice president and head of GSK's European Center of Excellence for External Drug Discovery. "It RNA-targeting drugs appear to be uniquely suited to treat disorders caused by expression of mutant proteins, protein overproduction or misfolding" (*Nat. Biotechnol.* 27, 874, 2009).

Mark Ratner

Observers noted that the attempted reauthorization of the DoD sections was adopted in the Senate rather than the House version of the bill, but it's unclear whether that will carry any weight in the ongoing debate. The actions of the Armed Services committees do, how-

ever, make it clear that the program, at least in some form, has a future. "If it's not reauthorized within the next year by the small business and science committees, then I think you'll see DoD doing it on its own," says Glover.

Karl Thiel Portland, Oregon

Biotechs get \$1 billion windfall in R&D tax credits

A small amendment to US healthcare reform legislation may prove a big boon for bioscience companies. It would create a \$1 billion "credit to encourage new therapies," allowing small companies (defined as under 250 employees) to write off half their R&D costs or, if they aren't profitable and don't pay taxes, to get an equivalent treasury grant. The amendment, introduced by Sen. Robert Menendez (D-NJ), is modeled after tax credits for alternative energy projects added to the US economic stimulus bill earlier this year. It has been attached by the Senate Finance Committee to the America's Healthy Future Act of 2009, which was introduced by Sen. Max Baucus (D-Mont.), and will become law only if this sweeping reform legislation is enacted. The Biotechnology Industry Organization (BIO) wanted the legislation in the stimulus bill but found legislators more receptive for its inclusion in healthcare reform.

"We are thrilled that the committee chose to pass the amendment," says Alan Eisenberg, BIO's executive vice president for emerging companies and business development. With the Baucus bill passed out of the Finance Committee, the Menendez amendment is very likely to remain part of the language ultimately voted on by the full Senate, assuming the bill reaches a vote.

Only R&D conducted in 2009 and 2010 is eligible for the program. The credits and grants apply only to qualified "therapeutic discovery" projects, which would be determined by the US Treasury Department, working in conjunction with the US Department of Health and Human Services. Qualifying programs must "show reasonable potential," with a focus on unmet medical needs, particularly cancer, and reduce healthcare expenditures. There is no specific limit on the credit any particular company can receive, which means \$1 billion will be awarded on a first-come, first-served basis. There should be no limit on competition for the awards. Eisenberg notes that over 90% of BIO members fall under the definition of 'small companies' eligible for the program.

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SELECTED research collaborations

Partner 1	Partner 2	\$(millions)
Amylin (San Diego, California)	Takeda (Osaka, Japan)	1,075
Alder Biopharmaceuticals (Bothell, Washington)	Bristol-Myers Squibb (BMS) (New York)	1,049
Micromet (Bethesda, Maryland)	Sanofi-Aventis (Paris)	473,59
Medivation (San Francisco)	Astellas (Tokyo)	765
SuperGen (Dublin, California)	GlaxoSmithKline (GSK) (London)	383
Endotis Pharma, (Paris)	Catalent (Somerset, New Jersey)	*