IN brief

Vatican cheers GM

A closed door meeting to be held at the Vatican in Rome in May will see leading scientists gathering to discuss a campaign backing agricultural biotech. The study week has been organized by Ingo Potrykus, co-inventor of the fortified Golden Rice technology and president of the Golden Rice Humanitarian Board, on behalf of the Pontifical Academy of Sciences. The Vatican has long been concerned about food security, and advisors from the academy, which holds a membership roster of the most respected names in twentieth-century science, have recognized that plant biotech has the potential to benefit the poor. "I think we are heading in the right direction with this meeting and it will help to dispel some of the myths about GM crops," argues Peter Raven, director of the Missouri Botanical Garden in St. Louis and an academy member. Participants are expected to issue a definitive declaration and work on a roadmap for science-based regulations for genetically modified (GM) crops. "I would hope the moral high ground of the Vatican is relevant at least in Catholic countries," says Potrykus, whose Golden Rice project has been held up by political hurdles. It will be particularly interesting to see reactions in Italy, where a nine-year ban on open field trials recently ended. Some of the 'regions', into which Italy is subdivided, "still jeopardize field studies by failing to identify [planting] locations," says Piero Morandini of the University of Milan. *Anna Meldolesi*

China overhauls patent law

China's top legislature has amended its patent laws in a bid to support domestic innovation and entice foreign biopharma companies to do business in the country. The revised law, passed late last year by the Standing Committee of the National People's Congress, will take effect on 1 October. The intent is to raise the novelty benchmark by requiring that a patent application must be new worldwide. In the past, patents could be granted as long as the technology was novel in China. The revised law will allow inventors to apply for patents in other countries before obtaining them domestically. They must, however, first get an approval from China's patent administration department, which will determine whether the invention should be made a 'national secret'. The development is welcomed by the international patent community, says Michael Vella, head of the Shanghai-based China Intellectual Property Practice. "It is a signal that China's patent law is increasingly brought into line with international standards." The revised law should encourage foreign companies to do business with China, says Vella, by increasing patent enforcement. The new law also allows the granting of a compulsory license in cases of national emergency, and includes a provision requesting that patent applicants disclose the source of materials to affirm that they are lawfully obtained. "China will be the first major economic power that requires this," says Vella. *Jane Qiu*

says those worries are misplaced because of the extensive purification steps that the company takes to produce hES cell–derived oligodendrocyte progenitor cells. "These aren't totally undifferentiated cells, but rather, they are 90% of the way to being a glial cell. Getting the cells to that state is a critical part of the manufacturing process, and it's integral to every product we're developing."

The bigger worry is that any safety issues that arise during Geron's clinical trial could have a devastating impact on the ability of stem cell companies as a group to raise funds. "We do worry about the potential negative impact a safety signal could have in this trial on the investment community, particularly among those investors that don't have a lot of history in the regenerative medicine space," says Joseph Pantginis, senior vice president at Merriman Curhan Ford in San Francisco. "Safety is obviously an issue, but having said that, you just have to look at the 22,000-page IND to see that the company went out of its way to address the potential for adverse events." And on a lighter note, Neuralstem's Garr adds, "The venture capital community hasn't been in this space for years, so I don't worry about scaring anyone off should Geron's trial run into trouble, which I actually don't expect."

Safety concerns aside—and the verdict will be out until phase 1 trials are complete in late 2010 or early 2011—researchers and investors alike worry that Geron's hES cell–derived oligodendrocyte progenitor cells simply won't work. "It's hard to think of an indication more difficult to treat than severe spinal cord injury in a human," says Aileen Anderson of the University of California, Irvine, who has had some success in using stem cells to treat spinal cord injury in rats. One issue is that the rodent spinal cord and primate spinal cord differ markedly both functionally and physiologically, "so extrapolating from rats to humans is not straightforward," she explains.

Of particular concern, says Arnold Kriegstein of the University of California, San Diego, is the fact that patients can experience some improvement in function without treatment, and so unless the positive effects of stem cell treatment are marked, phase 1 results could prove equivocal. "There's a real problem for Geron in that there is no way to track the fate of these cells once they are injected into the patient," he explains, "so in the absence of a big clinical response, which I'm not expecting, we may not get an answer as to whether this approach works or not."

Then there is the matter of perception and hype. On the day Geron announced the trial, the company's phone system crashed under the influx of calls from patients wanting to take part in the clinical trials. "This is a landmark study, potentially game changing, but expectations need to be realistic," says Pantginis. "We can't expect people to get up and walk following this therapy. Even the most optimistic of us don't expect that to happen." Indeed, experts such as Kriegstein, Carpenter and Anderson all agree that an improvement in lower body sensation or bladder control would represent huge benefits to patients.

In the meantime, Geron and others, including Neuralstem, BioTime, ACT and Stem Cells in Palo Alto, California, are pushing ahead with other stem cell–derived products, and Carpenter, for one, believes that everyone in the field owes Geron a debt of gratitude. "Geron has had such a difficult road," she says. "The company has been in the spotlight for years and it's been criticized up and down, but to its credit, it persevered, and as a result, everyone in the field is benefitting. And despite the safety concerns, the bottom line is that this trial is not premature. The safety of Geron's stem cell product has been tested as well as the current animal models allow. The next step is to take these stem cells into humans."

Joe Alper *Louisville, Colorado*

SELECTED research collaborations

Partner 1	Partner 2	$ (millions)
Micromet (Munich)	Bayer Schering Pharma (Leverkusen, Germany)	395
Santaris (Horsholm, Denmark)	Wyeth (New York)	100
Arcadia (Davis, California)	Advanta India (Bangalore)	*

* Not disclosed.