



Biobusiness Opinion

Reining In New Therapeutic Hype Is Critical

Finding the Middle Ground Between Biotech Executive Optimism and Practitioner Pessimism

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In the April 2008 issue of *BioExecutive International*, Hagen et al., noted that “in presentations by biotech executive investors, seldom is presented a discouraging word.” In the article, the authors encouraged these executives to translate their enthusiasm into language the investment community (which would include larger pharmaceutical licensing partners) would value.

Inherent in that value proposition would be a realistic appraisal of the risks and costs involved in developing the product, and the return available from a market of practitioners enthusiastically using the product.

This is one of the critical challenges for biotech executives—to see beyond their own natural enthusiasm for an emerging treatment possibility and the positive support of consulting medical thought leaders—who may be somewhat removed from the actual practice in market conditions.

Executives, wishing to promote their product and their companies, should endeavor to engage in the appropriate due

diligence to present the market opportunities and challenges realistically. On the other side of the fence, investors and licensing partners should be prepared as part of their own due diligence to seek perspectives from the trenches (if not proffered by the biotech company) to make the most informed acquisition decisions.

Business decision makers on the acquisition side of the fence also can be victim to the inherent enthusiasm of advice from their own thought-leader panels and consultants. In general, regardless of whether one is a biotechnology executive or a key decision maker with a potential acquirer, overemphasizing thought-leader input at the expense of clinical practitioner perspectives may create an unrealistically

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rosy picture on the potential uptake of a new medication in development.

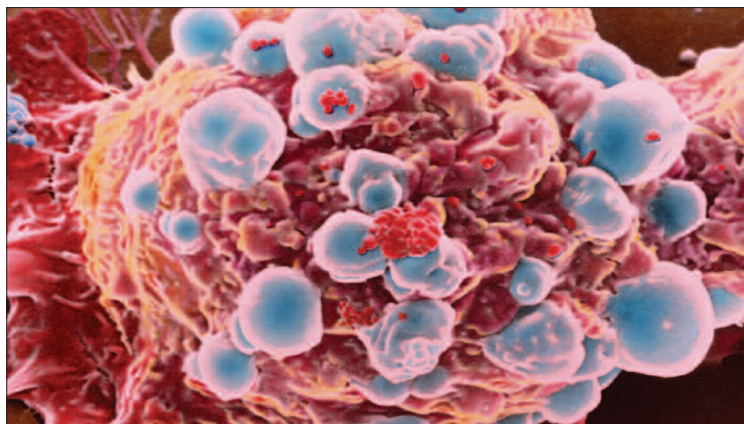
Media's Enthusiasm

To illustrate the potential disconnect between developer enthusiasm and the perspectives of physicians in the trenches in assessing the promise of a new treatment, we look to recent attention being paid in the industry press to what appears to be the exciting promise of therapeutic vaccines for cancer.

A good example is a November 15, 2007, *Genetic Engineering & Biotechnology News* story entitled “Advancing Cancer Vaccines.” The article, which summarizes the current state of this new

Scanning electron micrograph of a single breast cancer cell. In patients diagnosed early, new treatments can slow the growth of these cells.

Quest/Photo
Researchers



medication class, reports on the general wave of enthusiasm that was manifested among thought leaders at the “World Vaccine Congress.” Speakers and attendees of the conference were enthusiastic not only because of the promise of these types of medications in oncology but also because of the increased clinical trial support and funding on the part of major pharmaceutical companies.

Similarly, in the Editors’ Choice section of November’s *Science*, the editors point out the potential to “put a pox on cancer,” citing independent preclinical studies demonstrating that the vaccinia virus may be engineered to enhance the body’s anti-tumor response, and “therapeutic activity was seen when the viruses were administered systematically”.

To obtain a true picture of the ultimate demand for such agents, the perspectives of the clinicians who are responsible for treating a majority of cancer patients should also be assessed. Furthermore, it is here where there may be a disconnect between the general tenor of what thought leaders (and the story-hungry media) think and write about vaccines and oncology and what medical oncologists believe.

Oncologist’s Pessimism

Recent research conducted by Observant (www.observant.biz) suggests that practicing oncologists outside of thought-leader circles tend to be pessimistic about the potential for new agents and therapeutic vaccines in particular. As part of our in-house research and development program, Observant recently completed 20 in-depth interviews with medical oncologists to assess their perspectives on emerging therapies and unmet needs across the treatment landscape of breast, lung, and colorectal cancer.

To ensure that we spoke to practitioners and not thought leaders, potential respondents were prescreened to exclude those

associated with the pharmaceutical industry in any advisory or consultative role as well as those involved in clinical trials.

In general, we found that medical oncologists in the trenches recognize the importance of advances in treatment offered by drugs such as tamoxifen, Herceptin®, Avastin®, and Erbitux®. In patients diagnosed early, these oncologists are beginning to think of breast cancer as a chronic disease in light of the therapeutic success of new agents and other novel therapeutic approaches.

This positive regard for recent advances, however, may be superficial and mask a deeper pessimistic world view with regard to current and future treatment options, regardless of their focus. Additionally, this overarching pessimism can translate into a perception that patients and caregivers are unrealistic in their hopes for effective cancer therapies.

This pessimism reinforces a wait-and-see perspective on the potential of vaccine therapies. Our respondents recognize that vaccine technology could, in theory, be leveraged to develop effective therapies, especially for more easily targetable cancers like certain types of skin and colon cancers or cancers that are slower in developing such as prostate cancer. The lack of any apparent tangible progress to date in bringing a therapeutic vaccine to market reinforces a pessimism that for some borders on cynicism.

These attitudes are probably driven to some degree by the sheer volume of emerging positive early-stage information about potential new vaccines and other treatment modalities. This wave of information may be too large for practicing physicians to process or simply not relevant enough as it does not spring from later-stage clinical trials.

Among those oncologists who do see a potential for therapeutic vaccines,

they tend to see them having a limited role by patient type or stage of disease, and they do not anticipate anything entering the market soon.

Licensing and Marketing

It is clear that biotech companies, investors, and potential licensing partners need to consider the potential for in-market resistance among practicing physicians to information regarding the potential of new therapeutic vaccines (indeed any new product still in early stages of development). There is an obligation to all stakeholders in therapeutic vaccine development, and any cancer therapy, to not hype potential advances and further sour an already cynical consumer base.

This pessimism is a potential barrier to rapid trial and adoption of new medications, which is often critical to success in ROI terms. The antidote for this barrier, which has developed after a long history of failed medications and ones that have significantly underdelivered, is creating realistic expectations within the medical community of what a medication can potentially do. More accurate biotechnology forecasts and projections and related communications may increase initial trial and adoption of a new medication.

Furthermore, these projections, when they are communicated to investors and pharmaceutical companies, may have more impact if they are tempered with some sense of the barriers inherent in gaining acceptance of therapies in the clinic.

Much of the enthusiasm generated at the “World Vaccine Congress” was the increased willingness of pharmaceutical companies to fund clinical trial research. Such research should be accompanied by focused, relevant market research in the early stages that can provide key decision makers with a better sense of the true value proposition of a new medication. **GEN**