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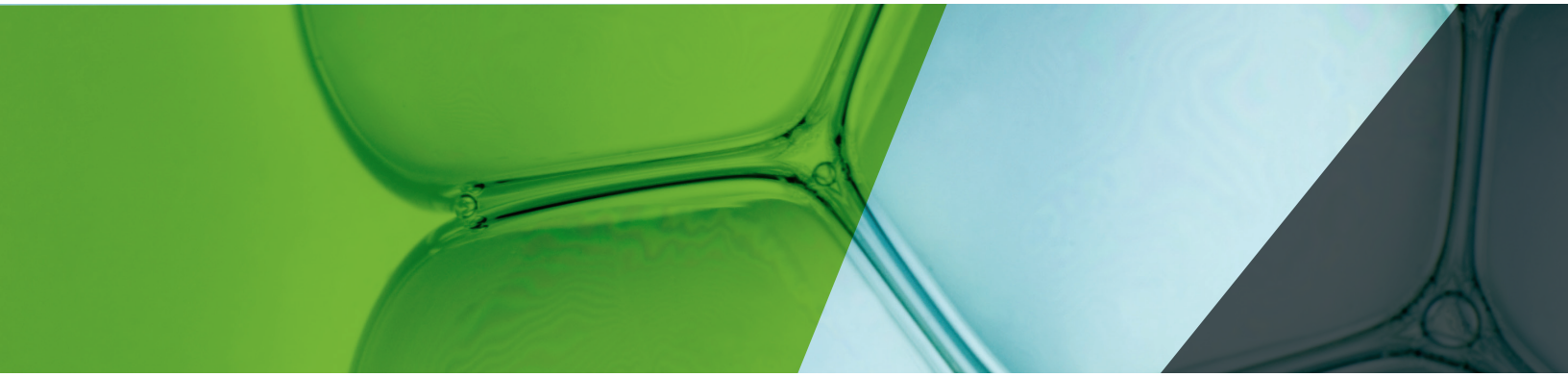

GLOBAL OEM DISCOVERS UNEXPECTED OPPORTUNITY FOR MINIMALLY INVASIVE EMBOLISM THERAPY WITH HELP FROM NAVIGANT

CHALLENGE

A global original equipment manufacturer (OEM) was preparing to launch a new minimally invasive embolism technology, but wasn't sure which market to focus the launch on.

The technology could be used in a variety of surgical procedures, and appeared especially promising in treating obesity or alleviating symptoms associated with osteoarthritis. The global OEM wanted to determine which one carried the best potential return on investment before committing resources to commercializing the product.

The initial hypothesis was that the obesity market was a top priority.

SOLUTION

Leveraging a comprehensive body of available research, Navigant conducted a landscape assessment to evaluate the market size, value proposition, and adoption barriers for the products in the U.S., China, Japan, Germany, and the UK.

Analysis: Obesity Market

At the outset, the obesity market appeared very encouraging. Because the new technology offered a minimally invasive option, it was best-suited for those patients who also had diabetes and for whom surgery was not an option. More than 35% of the adult population in the U.S. is obese. Diabetes affects up to 12% of the population with another 33% in the preliminary stages of the disease. When cross-referenced, this data appeared to present a sizable market with high associated costs to the healthcare community.

Furthermore, the new technology offered a less-invasive intervention option than standards of care, and presented a clear clinical benefit for a small fraction of the market.

However, research and analysis uncovered several critical barriers to adoption.

A level of high motivation was required on a patient's part to seek treatment. Most patients who sought treatment presented to general practitioners — not surgeons — who tended to recommend medical management of the condition or lifestyle modification, rather than standard of care gastric bypass surgery. In fact, fewer than 1% of patients received the intervention, and those who did had to first pass through an intricate approval process. Of the treated population, very few patients consistently complied with requirements of the surgery to sustain long-term positive weight loss. As a result of this behavior pattern, it would have been very difficult to isolate and prove the benefit of the new technology in a trial.

In order to spur interest in the new treatment option, the company would need to generate clinical data that proved long-term patient benefits vs. the current standard of care. It also would need to provide guidance on diagnosis of these ideal patients to trigger providers to prescribe the treatment option.

Analysis: Osteoarthritis Market

Over 650,000 patients in the U.S. develop osteoarthritis each year — and most are between ages 60-79. That figure decreased to 546,000 after eliminating patients who will never be treated due to contraindications and/or comorbidities. Of these, research showed patients who experienced a high level of bother from the primary condition but wanted to maintain high activity sought treatment, or 58,000.

While that figure at the outset seemed small, further examination of the current standard of care revealed a compelling opportunity for the new minimally invasive treatment option. In practice, nearly 100% of the perfect-candidate pool eventually underwent the standard of care, which was knee-replacement surgery. However, because people are now living longer, and since the most active patients are the ones who seek treatment the earliest, the artificial knees implanted into these patients are likely to wear out within a patient's lifetime and require revision surgery. The revision surgery tended to result in poor outcomes and significant complications. So, the global OEM could offer these patients a way to alleviate pain while delaying the need for a knee replacement.

Furthermore, a wide range of physicians could easily diagnose and refer or, depending on the specialty, treat these patients once the condition was diagnosed. Most of the patients in the ideal-candidate pool seek treatment from generalists, however. This created an adoption barrier, because a referral trigger and pathway needed to be developed and reinforced.

A lack of clinical evidence presented as another barrier to adoption. The global company needed to definitively demonstrate that its minimally invasive option restored function and improved the associated symptoms enough to warrant its use over its invasive predecessor. However, analysis revealed a strong link between the therapy and outcome, meaning few variables existed to potentially muddy the results.

While ideal patient pools varied in size in the other countries researched, the results of analysis of clinical trial risk and likelihood to adopt the new technology were largely consistent with the findings for the U.S.

IMPACT

Although the obesity market proved to be much larger, the arthritis market proved to be the better opportunity for the global company. It offered a clear clinical benefit to a more significant portion of a smaller market.

Navigant advised the global OEM to conduct further clinical studies to solidify evidence of the treatment option's efficacy within the arthritis market, as well as to develop guidance for physicians on use and ideal candidate selection. In addition, the company needed to evaluate potential reimbursement strategies and clinical pathways to help spur adoption of the technology.

As a result of Navigant's findings and recommendations, the global OEM abandoned the obesity market in favor of moving forward with creating an osteoarthritis plan for this technology.

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