

## Competitive Pharmaceutical Clinical Pipeline Analysis

### The Problem:

nxtMOVE's client was actively pursuing the development of a biological compound that would represent a next generation therapy in the treatment of a dermatologic condition that affects nearly 30 million people in the US alone. As the candidate was in early clinical development, the client needed to develop a greater understanding of what the competitive market landscape might look like in the anticipated time frame in which their product was expected to be approved and launched. This information was critical to the client in understanding how it might have to develop its clinical trial protocols in anticipation of competitive developments.

### The Solution:

nxtMOVE identified and then interviewed representatives of companies in the US, Canada, Europe, and Asia that were known to be or believed to have at least one compound in their clinical pipeline with a primary or secondary indication of the target disease. Through these discussions, nxtMOVE gathered information on the nature of the compound, the status of clinical trials, the anticipated launch timing, and how the product would likely be positioned in the market upon launch relative to placement in the treatment paradigm and in terms of current and other emerging therapies. nxtMOVE also interviewed several thought / opinion leaders in the disease field to obtain their insights into competitive development activities in the area as a means to provide additional depth and detail to the product map.

Competitive pipeline assessment: Phase III

	Compound	Stage of Development	Route of Administration	Comments
Company A	44567	Registration filed in Germany in 2005	Oral TID	<ul style="list-style-type: none"> <li>Primary indication: moderate to severe (Phase III completed in Germany. Filed with Germany authorities in 2005, approval is expected in second half 2006.</li> <li>Additional Phase III studies are planned for US. Timeline for these studies is still 'up in the air.'</li> <li>Dosing level will probably be 720mg TID, same as Phase III dosing levels.</li> <li>Hoping to replace current therapies, but Company A needs to see how market will use 44567 in the treatment paradigm.</li> <li>Company officials emphasize that it is very committed to this compound and the disease state as an indication, and believes it will have a significant impact on the market; again, replacing common products are already on the market.</li> </ul>
Company B	Tulip	sBLA was accepted by the FDA	Oral	<ul style="list-style-type: none"> <li>Supplemental Biologics License Application accepted by FDA for treatment of moderate to severe disease in 2005. Filing was based on two Phase III European trials.</li> </ul>
Company C	99810Z	Currently in Phase III extension study (data analysis)	Oral, twice daily	<ul style="list-style-type: none"> <li>Primary indication: moderate to severe (Phase III completed)</li> <li>Focused on 0.3mg/kg dose.</li> <li>Projected NDA file date is first half 2008</li> <li>Possible launch first half 2009</li> <li>Currently no plans to seek a marketing partner</li> <li>Strengths: Decrease in test scores at 12 weeks for 0.3mg/kg BID was 62 percent</li> <li>24 percent of patients discontinued Phase III trial for a variety of reasons. The largest grouping ("Other" (47 patients or 10 percent) includes individuals that withdrew consent, lack of efficacy, and trial fatigue. 12 patients (3 percent) experienced adverse effects including headaches, nasopharyngitis, hypertension, diarrhea, nausea, and fatigue.</li> <li>Secondary indication: Kidney transplantation (Phase IIa, Phase IIb began in January 2006).</li> <li>Other indications: rheumatoid arthritis, Type I diabetes, Crohn's disease, and liver, heart, and lung transplantation.</li> </ul>

### Client Response:

With detailed information on competitive product development activities and timing, nxtMOVE's client was able to make more informed decisions regarding the development of its candidate. In particular, the client was able to clearly identify those compounds that were likely to represent the strongest competitive threat to its own candidate and, as such, were worthy of continued monitoring relative to their progress through the clinical trial process. The client was also able to develop an understanding of what changes it would potentially need to make in its own clinical trial design to incorporate anticipated shifts in the treatment paradigm for this disease.