Dymista briefing document

The product: Dymista is a novel formulation of azelastine and fluticasone propionate in an advanced delivery system. The product has been positioned as a new allergic rhinitis product and not as a fixed dose combination. There is evidence that the formulation/device contribute to product characteristics as well as the 2 active principles. The product has been shown to be twice as effective as current 1st line therapy e.g. intranasal corticosteroids in reducing nasal and ocular symptoms. The most bothersome symptoms of AR are nasal congestion and ocular itching. Dymista is twice or even three times more effective than intranasal corticosteroids in reducing those symptoms. Furthermore Dymista is superior regardless season, symptom, and severity. Leading experts including the editor of JACI (the most prestigious allergy journal) consider Dymista the drug of choice for moderate to severe AR. Publications will be made available via the brand portal.

Label of the product: The label of the product is different. Dymista has a SAR label in the US, a SAR/PAR label for moderate to severe AR patients in Europe, a SAR/rhino conjunctivitis label in Switzerland and a SAR/PAR/rhino conjunctivitis label in Australia. Meda will send agency an overview of the label in the various countries. Various country labeling will dictate what product attributes mentioned above may be utilized (e.g. the US label does not include ocular symptoms, regardless season, or "twice as effective").

Positioning of Dymista: There is an unmet medical need for a faster and more effective allergic rhinitis (AR) therapy in moderate to severe patients. Up to 90% of patients already use combinations of existing mono therapy in an attempt to control their AR symptoms. Dymista shall be positioned as the first line therapy for those patients. This is the vast majority of AR patients who are seeking medical help. Dymista shall be positioned as a new AR therapy and not as a fixed dose combination.

Launch positioning and physician perception of the product in the US: Meda US did not follow the global strategy and reinforced physician perception of Dymista as a fixed dose combination. The graphics did also emphasize the existing physician perception by using a 2 color Trademark and a two color design in the overall branding. As a result Dymista was reserved for late in the treatment algorithm. This positioning turned out to be overly restricted and, in turn adversely affected patient access through managed care payers. As stated by investors: "the cost/benefit profile of Dymista versus cheap generic standard-of-care (fluticasone) is simply not good enough for a commercial success and that lack of payer support will continue to hamper the uptake". Several payers did not grant Dymista unrestricted access (Tier 2 and Tier 3) arguing that the premium price is not justified (approx. 2.5 times higher than the lose combination generic equivalent). Experts consider to use the lose combination of Fluticasone propionate and Azelastine nasal spray which are commercially available, claiming "the superiority of Dymista does not offset the additional hassle a higher price and less favorable formulary status implies".

Importance of Dymista for Meda AB: Meda is the leading Swedish company with overall sales of approx. 2 billion US$. Dymista has to be the growth driver for the next 5 years must reach approx. 1 billion US$ net sales in the US, more than 250 million € net sales in Europe and approx. 200 million € in the rest of the world. Dymista and especially Dymista in the US are in the focus of financial investors after the placed on improving the current growth trajectory of Meda US in spite of declining branded AR markets.

Current sales development: Dymista was launched in September 2012 in the US and in some European countries 2013. Dymista sales are clearly behind expectations in the US with an approx. 1.5% market share in units of the intranasal corticosteroid market (which is used as benchmark) and 4% market share in US$. The launch has been successful in some European markets e.g. Ireland, Germany, Austria, Finland, Sweden where a market share of 4-12 % in units (8-25% in Euro) has been achieved. This provides some proof that the positioning of Dymista is predicated on the right combination of market pricing and clinical advantages.

Branding: The branding has been developed by the marketing center within Meda, which is located in Germany. An overview of the branding elements will be provided.

- Meda US used an own branding which was not in line with Meda Germany. One task of the agency is to advise Meda AB how to achieve global alignment and strengthen the branding.

Marketing materials: The marketing materials for Dymista have been developed by the marketing center and are located on the brand portal. The agency will have access to the brand portal. Agency has to review these materials and, if necessary, make proposals how to improve those.

- Meda US has, as mentioned above, used marketing materials developed in the US, e.g. sales folder, patient brochure. The quality is not acceptable for Meda AB. The most urgent priority of the agency is to adapt the existing US marketing materials. Agency must have a good track record in navigating US legislation in order to generate marketing materials, which are both compliant and assertive in their positioning. Meda needs the agency to advise Meda AB and Meda US how to achieve that position.

Pre-marketing and launch activities: Agency will review pre-marketing and launch activities of countries which will launch the product in the near future e.g. Australia, Canada, Mexico, Middle East, South Africa, Russia and make suggestions (if needed).

Publications: A global publication plan has been developed and key publications have been written. Previously, alignment between Meda US and Meda AB regarding publication planning and content has not existed. While some progress has been made, these conflicts have not been entirely solved. The agency must review the publication plan and make suggestions for alignment, if needed. The overall aim of the publication plan is to maximize the competitive profile of Dymista.

Life cycle studies: Life cycle studies have been discussed with leading experts and the 1st wave has been initiated. Agency has to review if the current life cycle plan will provide Dymista with further growth. Dymista must become a block buster product.

- Agency has to assess if the current US indication (SAR) is sufficient to provide product with approx. 1 billion net sales.

Dymista web site: The Dymista web site is fully developed. The agency will have to review the Dymista web site and if necessary make proposals how to improve those. Agency will also provide suggestions how to generate traffic to the web site.

- Again, quality of digital materials differs between Meda AB and Meda US and should be aligned as regulation allows. One priority of the agency is to update and improve the US web site.

Meda as a global AR player: Meda is not known as a company nor recognized yet as a major player in allergy. The presence at international as well as local congresses is therefore very important. Meda AB has by far the biggest booth (twice as large as other companies) at the EAACI and ERS congress and by far the highest number of poster/oral presentations (approx.. 20) and symposia among all companies (4).

- In the US, Meda also has a dominant presence at congresses. However, certain activities differ from that of the European congresses. The agency has to review the congress activities and assess if the current presence is appropriate, and if needed, improve and increase that presence.

Meda is lacking adequate pre-marketing activities to attract participants and lacks also follow up activities of these participants on a global level.

International KOL management: Meda AB has established productive relationships with leading European AR experts including the chairmen of ARIA. Challenges have arisen when attempting to manage the activities of US thought leaders and principal investigators of Dymista trials when engaged in ex-US activities. The agency has to assess the perception of Meda AB and Meda US with regard to US experts to understand the perception of Meda, and if the internal conflict has been recognized and negatively impacted the relationship.

Meda AB does not fully understand the extent in which local and international experts are integrated in the promotion of Dymista or the effectiveness of those activities. Agency has to assess the role of experts in the promotion of Dymista.

Sales force related activities: Market research on sales force effectiveness has been done in some countries. The agency has to assist Meda in the roll out of a sales force effectiveness program in close cooperation with market research. Meda will provide agency with market research and its results.

Non-sales force related activities: Meda is too focused on sales force related activities as a stand-alone growth driver and has not fully developed effective non-personal promotional campaigns. There is a clear gap in the understanding of how to run for example PR activities: press/broadcasting/TV and DTC activities.

Meda has a digital marketing department in Sweden and is initiating e-mail marketing activities for Dymista. Additionally, we are establishing a digital tool called Meda connect which links doctors to an interactive multiproduct web page. The agency has to review the non-sales force related activities and, if needed, improve those. The agency has to come up with a global PR plan.

Interplay of all marketing tools: Meda has no systematic approach how to link personal, non-personal, congress activities and experts to one unified communication strategy. The agency has to provide guidance as well as tools.

Global tasks of the agency:

Agency must review all Meda activities as well as current positioning and communication strategy.

Agency must identify all gaps and must provide a global communication/marketing plan including, congresses, key opinion leader management, sales force and non-sales force related activities. Agency must provide content and tools for activities where Meda lacks knowledge and infrastructure e.g. non-sales force related activities/interplay of all marketing tools.

US tasks of the agency:

Agency must provide Meda AB and Meda US asap with a plan how to change/improve positioning and branding of Dymista. Agency must adapt marketing materials/web site asap to the corporate guidelines.

Agency:

Agency must be global and must have an unbeatable track record in generating global blockbusters in the pharmaceutical industry. Agency must also have a track record how to deal especially with the US legislation and how to manage US compliance issues. Agency must have the capability to advice Meda how to overcome potential compliance issues with their suggested marketing campaign/materials. Agency must have a track record not only to generate the content/activities but also to implement measures to all Meda affiliates (US, Canada, Mexico, Europe, Australia, Russia, South Africa, Middle East Turkey)

Agency must present their entire team to Meda. Members of the team must have a certain seniority level and have successfully managed blockbusters. Members of this team shall exclusively work on this project.

Reporting:

Agency will report defined milestones and deliverables to a Steering Committee consisting of:

- Jörg-Thomas Dierks (CEO)
- Hans Tritschler (Executive Vice President Marketing Rx)
- Dirk Groen (Executive Vice President Marketing OTC who is also responsible for digital marketing)
- Maria Carell (EVP North America & Australia)
- Ton van't Hullenaar (EVP Europe & Latin America)
- Esfandiar Faghfouri (EVP Europe, Asia & Africa)
- Joachim Maus (EVP Scientific Affairs)

The Dymista Marketing Group, which will be the agency's primary point of contact, is consisting of:

- Hans Tritschler
- Stuart Loesch (VP Marketing Meda US)
- The European Dymista marketing team
- The US Dymista marketing team