HIGHLY CONFIDENTIAL -SUBJECT TO STIPULATED PROTECTIVE ORDER

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CIP2082 Argentum Pharmaceuticals LLC v. Cipla Ltd. IPR2017-00807



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Summary of Key Insights & Implications DYMISTA PHASE II - POSITIONING EXPLORATION



RESEARCH OBJECTIVES



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The objectives for the Phase 2 qualitative research were as follows:

•Expose and assess reactions to three alternative Dymista (unbranded) story flows.

- Each with a different opening context, and leading to a different set of core benefits and brand positioning
- Identify positioning direction(s) with strongest potential to motivate HCP trial
- Understand which individual story components are most compelling and best support the core positioning

METHODOLOGY



A total of 18 in-depth interviews (IDIs) were with healthcare professionals were conducted as follows:

- 14 with physicians
 - 4 allergists
 - 2 ENTs
 - 8 PCPs
- 4 with NPs/PAs

All interviews lasted approximately 45 minutes.

The research was conducted in Chicago, IL, and Atlanta, GA, on July 6-7, 2011.

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NOTE AND CAVEAT



Note

Verbatims in this report are reconstructed from the moderators' notes. We seek to accurately
represent each panelist's intent, though the quotes may vary slightly from a precise
transcription.

Qualitative Caveat

Qualitative methodologies seek to develop insight and direction, rather than quantitatively
projectable measures. Although consistencies and logic lend confidence to the analysis and
interpretations, this research must be viewed as directional rather than conclusive.

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Physician/HCP Interviews

Of the three alternative positioning directions we assessed, the most compelling would appear to be the "rapid and sustaining" story (Option #2).

- HCPs were particularly motivated by the notion of the two mechanisms of action in a single spray, resulting in the dual benefit of short- and long-acting relief.
- Strong recognition that INS is the category gold standard and that its one glaring deficiency is the inability to work quickly. Thus, this is a way to use INS but also get the rapid onset of relief from the antihistamine, all in a single product. Even low/non-writers of topical antihistamines give them credit for rapid relief, so there is no issue of credibility.
- Option #2 also comes across as the simplest and most straightforward story of the three, to the
 point that several said this is the way they would explain it to their own patients.
 - "This is how I'd explain it to my patients. You get two bangs for the buck."
 - "This breaks it down more simply; I like that."
 - "It's like I would tell them ... one opens you up and the other gets rid of the wall of inflammation."
- Note that the concluding point of the statement "rapidly knock down symptoms while the allergy season is still active" was not the basis for appeal. The episodic nature of allergies is well acknowledged, yet the rationale for choosing this positioning was not directly tied to getting relief within a short season.

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Physician/HCP Interviews

There were elements of the "convenience/compliance" positioning (Option #3) that were also quite compelling, and a few HCPs felt it was the strongest approach.

- HCPs widely acknowledged that getting certain patients to take a spray antihistamine (or any spray, for that matter) can be challenging. Adding a second spray, particularly when antihistamines are available in a convenient oral form, is something the majority are reluctant to do until patients have first failed on the oral.
- The logic of this story is fairly simple and there is no argument that Dymista will lead to greater convenience and better compliance compared to taking the two sprays separately.
- But where the story lost some doctors was in the presumption that they've "wanted to combine nasal antihistamines and steroids for years." Frankly, many have been content to continue them on their easy-to-take oral and just combine it with a corticosteroid when needed.
- Further, many did not feel it's that all that "complicated" to prescribe two sprays. Most felt the difference between one and two sprays is not huge, in terms of nasal volume or compliance - it's difficult to get patients to just comply with one.
- A few doctors really sparked to the notion of cutting out a copay, but clearly this cannot be a major selling point until they understand how Dymista is going to be priced.
- Net, the "convenience/compliance" advantage is meaningful but, for most doctors we
 interviewed, was just not as compelling an argument as the logic of Option #2.

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Physician/HCP Interviews



The "better efficacy" story (Option #1) was easily the least compelling of the three.

• The issue was not the basic argument being made that Dymista is more potent than the leading current option (INS) alone. In fact, several doctors agreed with the approach, in principle.

- "If they're miserable, I blast them. My theory is don't' wait. Better to blast them, then cut back later.""

- The story did not resonate that well for several reasons, the first of which is that most HCPs do
 not like to think of their approach as "guesswork" or "trial and error." With a bit of probing, most
 readily agreed they often try several approaches/combinations before they find success. But to
 call out their "guesswork" as the problem being solved here did not sit well with the majority.
 - "When I was younger, I would have liked this more. But now I have my strategy." "I don't 'cycle through.' I find what's best for my patients." "We don't believe we do guesswork. That's insulting." (ENT PA) "Maybe PCPs feel it's guesswork but we don't."
- Further, the concluding statement "ending the trial and error approach to treating SAR," is simply not credible for most HCPs. Yes, the product could potentially reduce a step or two in the pursuit of finding relief, but the condition will always require an approach that is not so cut and dry. And, while they philosophically love the notion of "reducing the burden" on the entire healthcare system, it just felt like an over-promise for this product concept.
- Finally, just about every respondent agreed this statement did not read as easily and the logic did not flow as simply as the other two statements.

 – "I don't like it as much; just not as straightforward." "This feels more technical, more complicated." MDP-044511K



Physician/HCP Interviews

Of the 15 statements respondents were asked to prioritize, seven rose consistently to the top. Based on the "10-chip" exercise, they are listed here in order of *relative* importance:

- (1) Provides both rapid and sustained relief was on just about everyone's "top 3" list and accumulated double the amount of "chip" allocations as any other statement.
- (3) Significantly better than fluticasone was a "top 3" selection for only a few HCPs but all placed the majority of their "chips" on this statement. Net, while there may only be a small portion of HCPs who will use Dymista for this reason, the idea that we have significantly improved the gold standard is highly compelling for them.
- (5) Eliminates the financial burden of multiple copays most respondents placed a small amount of "chips" on this factor.
- (2a) 1 spray instead of 2 This was a "second most important" advantage for several HCPs.
- (2b) Provides rapid symptom relief in as little as 30 minutes linked strongly to the "rapid and sustaining" advantage and a key reason the combination spray will be used over INS alone.
- (4) Significantly improves nasal <u>and</u> ocular symptoms somewhat of a surprise to see and there is still some skepticism here but if clinically true, this is a meaningful "additional" advantage.
- (2c) Reduces the number of allergy medications patients have to take similar to "1 spray vs. 2."

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Recommendations for moving forward:

- The "rapid and sustaining" positioning would appear to be a solid and compelling foundation for marketing Dymista.
 - "Rapid relief" is a logical/credible benefit of the topical antihistamine and a meaningful enhancement to the category gold standard, intranasal steroids.
 - It aligns with physician's overarching need/desire for "efficiency." Few doctors would argue that getting the benefits of two products in a single medication is an advancement.
 - Getting both in a single spray is a fundamental reason many will use this product.
- Bringing in some of the "convenience/compliance" advantages from Option 3 should enhance the "rapid and sustaining" story considerably for many HCPs.
 - In particular, making the point about taking "only one spray" and the notion of "only one copay" has both logical and practical advantages for physicians. Especially for those who lean strongly toward prescribing what they feel is most cost effective and easiest for their patients.
 - These Dymista advantages would seem to be particularly compelling for PCPs, many of whom prioritize these factors over what they feel is the most effective solution.
- Finally, we believe the positioning can be further enhanced and supported by weaving in the "first and only" language. This helps call out the uniqueness of Dymista, which is important for those who feel "I've been doing this all along." It should also provide the halo impression that this is truly an "advancement" in allergy treatment.

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Key Considerations

- **Rapid and sustained** gives HCPs more than what they get from INS and oral antihistamines; single spray provides permission to use nasal antihistamine
- Tried and true medicines leverages what they know providing comfort... however, non-azelastine users have never used these medicines this way (proceed cautiously)
- "Advanced" provides a nod to the formulation, suggesting that independent use of these medicines will not get the same results as Dymista (don't overstate..."novel")
- First trial, successful trial... will drive satisfaction with NRx and consumption of refills (think next allergy season and household-preferred medication for SAR)
- Efficacy is more than a % it is "symptom reduction." We need to translate our % advantage into outcome expectations (symptoms drive the bus)
- Major trapdoor: HCPs sample Dymista for 1 week, then Rx fluticasone using Dymista or give Astepro 0.15% samples PRN.

Dymista Positioning

POSITIONING STATEMENT OPTIONS

Rapid and sustained relief

- To: HCPs who treat patients with seasonal allergic rhinitis (SAR)
- **Dymista is the:** only treatment to prescribe when a patient's allergy symptoms continually interfere with their day-to-day lives
- That: provides both dimensions of efficacy—rapid <u>and</u> sustained symptom relief formulated in one spray
- Because: it is the first and only medication to combine two tried-and-true agents, thereby providing the persistent control of a corticosteroid (fluticasone) coupled with the immediate relief of an antihistamine (azelastine)
- So that: patients can have superior, fast, and long-term symptom control in a single convenient spray they are more likely to adhere to using

First and Only

- To: HCPs who treat patients with seasonal allergic rhinitis (SAR)
- **Dymista is the:** only treatment to prescribe when a patient's allergy symptoms continually interfere with their day-to-day lives
- That: is the first and only intranasal corticosteroid to include a nasal antihistamine in a single highly effective and convenient spray
- Because: it applies advanced, structured suspension technology, providing a simultaneous, uniform, and consistent delivery of both fluticasone and azelastine
- So that: patients can benefit from unparalleled efficacy, and experience the sustained relief of a corticosteroid and the rapid onset of action of a nasal antihistamine in a single prescription

Efficacy you can rely on

- To: HCPs who treat patients with seasonal allergic rhinitis (SAR)
- **Dymista is the:** only treatment to prescribe when a patient's allergy symptoms continually interfere with their day-to-day lives
- That: finally improves efficacy in a way you can rely on
- Because: Dymista is an advanced formulaton that combines two tried and true agents in a single convenient formulation—providing superior efficacy to fluticasone and azelastine for both nasal and ocular symptoms
- So that: by using a single spray, you can stop the allergy symptoms that continually plague your patients

Unparalleled efficacy with convenience

- To: HCPs who treat patients with seasonal allergic rhinitis (SAR)
- **Dymista is the:** only treatment to prescribe when a patient's allergy symptoms continually interfere with their day-to-day lives
- That: provides unparalleled efficacy with easy-to-take convenience
- **Because**: in a single spray, you get the efficacy you've always wanted by combining the persistent control of a corticosteroid (fluticasone) coupled with the rapid relief of an antihistamine (azelastine)
- So that: in a single prescription medicine that is specifically formulated to be a catalyst for compliance, patients can have significantly superior SAR control compared to either agent alone—without the need for multiple sprays

Meda Allergy Franchise: The Clinical Foundation

- To: patients suffering from allergies and the HCPs who treat them
- Meda Pharmaceuticals is the: leading dedicated partner providing cutting-edge allergy medications and services to HCPs and their patients
- That: provides therapies and support systems that help HCPs and their patients relieve the symptoms of allergic rhinitis
- Because: only Meda has successfully focused research into proprietary nasal formulations that provide uniform and consistent delivery of both highly effective single agents and drug combinations
- So that: patients get the symptom-relieving medications they need, and HCPs can feel confident in prescribing category-leading products from Meda at any point in the continuum of care

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