Market Shaping for New Categories in Advance of Approval

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12:00 pm – 1:00 pm
North Carolina Biotech Center
My Perspective and Why

• I run a specialized integrated communications and marketing agency in health and science innovation

• Our clients are either:
  – Emerging companies
  – Or, growth companies in the process of commercializing
  – Private and public entities

• Our client work is dedicated to helping our clients realizing their visions through market shaping, marketing and public education/awareness.

• Many times our client’s products/product candidates are new categories or new entrants
Key Audiences to Consider for Market Shaping

- Establish and prioritize client’s key audience
- **Earlier-stage** companies main focus includes: investors, media and partners, industry
- **Later-stage** commercial companies expands to governments (US/EU), regulatory bodies (US, EU, Asia), advocacy (in particular patient groups), industry organizations, professional societies
When is the Sweet Spot Timing to Begin?

CRITICAL TIMEFRAME TO BEGIN, THROUGH APPROVAL AND POST-MARKETING ADJUSTMENTS
Case Study 1: New Category in Advanced Breast Cancer

Situation Analysis

- Menarini is not well known in oncology arena; acquired asset from Stemline
- Metastatic breast cancer has had little or no innovation in over 20 years
- Headwinds as large pharma’s work in the category did not deliver on successful outcomes
  - Sanofi withdrew after Phase 3, Roche, failed in Phase 2, AstraZeneca still in hunt
- Low visibility going into potential FDA approval (as reported by market research by HCPs/oncologists)
- ORSERDU, is a first and only oral endocrine therapy that treats metastatic Estrogen Receptor Positive Breast Cancer with ESR1 mutation (approved Jan. 2023)
ESMO 2022 – Sanofi and Roche’s duelling Serd duds

The only novel oral SERD to work so far has been Radius/Menarini’s elacestrant, likely thanks to its trial having been enriched for ESR1 mutants. Curiously, however, this project is not being tested in the front line.
The Change They Wanted

- Create market shaping, visibility and awareness through broad coverage in oncology, medical and trade media publications highlighting the drug, its clinical benefits and opportunities for success as an mBC treatment.
- Carefully manage while company was in late registration phase and label discussions underway.
- Leverage the first U.S. approval to drive visibility for the Menarini Stemline Oncology division in U.S.
What We Did

- Audience prioritization – focus on oncology community
- Conducted Messaging & Positioning to solidify corporate and brand message – The LHS Immersion®
- Create storylines aligned with prioritized stakeholders
- Identified misconceptions and corrected them
- Built communications strategies to educate oncologists on clinical outcomes
- Increased US brand awareness and reputation through relationships with key media
- Soft-sounding interviews on background
- Developed media room materials, FAQ’s, bios, holding statement, images, fact sheets, digital
- Scenario planning ahead of approval
- Identified and media trained KOLs
- Pulled through FDA approval with label criteria set
The Change We Delivered

- Cohesive, integrated communication strategy that successfully exceeded KPIs - securing articles in 91% of oncology and industry trade pubs including *Targeted Oncology, OncLive, OBR, Cure, Healio, FiercePharma, BioCentury, BioWorld, EveryDay Health*

- **Strong KPIs with paid newsletter campaigns targeted to community oncologists**

- Positioned ORSERDU as the first new endocrine **therapy in over 20 years** and the only oral therapy specifically indicated for patients with ESR1-mutated advanced or metastatic breast cancer

- Increased awareness of the ESR1 mutation and the unmet treatment need in late-stage disease

- **Strong media coverage consisting of 763 earned and syndicated articles with over 1.25B unique visitors per month (UVM)**

- **Strong journalist engagement with 9,243 shares and an audience reach of 1.69M**
Where Big Pharmas Faltered, Stemline Succeeds and Lands FDA Nod in Breast Cancer

...Orserdu, a drug from Menarini Group subsidiary Stemline Therapeutics, is now approved for treating breast cancers that carry the ESR1 mutation. The drug is the first approved oral therapy from a class of therapies called selective estrogen receptor degraders (SERDs).

• By FRANK VINLUAN

Jan 31, 2023 at 7:22 PM
Increasing Visibility for FDA Product Approval

Menarini shows Big Pharma how it's done with first approval for oral SERD drug in breast cancer

FDA Approves Orserdu for Metastatic, Estrogen Receptor-Positive Breast Cancer

The FDA has approved Orserdu, a new oral medicine to treat metastatic, estrogen receptor-positive, HER2-negative breast cancer with an ESR1 mutation.

After 30 years of research, pill for breast cancer approved for use

FDA approves elacestrant for advanced breast cancer

Orserdu Approved for Metastatic Breast Cancer Represents ‘Big Breakthrough’

MedCity News

New Hormonal Treatment Orserdu Approved for Metastatic Breast Cancer

Where Big Pharma Failed, Stemline Succeeds and Lands FDA Nod in Breast Cancer

Medical Press

FirstWord PHARMA

FDA Approves Stemline’s oral SERD for ESR1-mutated breast cancer

LaVoie HealthScience
Questions?
Case Study 2: Building Acceptance of Biosimilars

Situation Analysis

• Samsung Bioepis is a biopharmaceutical company focused on advancing a broad pipeline of biosimilars candidates that cover a range of therapeutic areas.

• Samsung Bioepis is a sponsor but not the marketer of several biosimilars being launched in 2023 and beyond.

• Samsung Bioepis wishes to be recognized for its product development and commitment to quality.

• Market shaping needs to be done “above brand” and needs to work within marketers plans for good alliance management.

• Need to expand footprint with key US stakeholders and increase understanding and acceptance of biosimilar market
The Change They Wanted

- Expand the footprint with key U.S. stakeholders and increase their understanding and perception of the biosimilar market
- Enlist a strategic partner with global reach to connect with key stakeholders and target audiences
What We Did

- Identify and develop strategic communication plan
- Develop storyline, content on the key issues, audiences and arguments - pricing, reimbursement reliance on partners, perception general public
- Monitor competitor intelligence and partner news
- Establish communication channels and plan
- Developed a White Paper based on closed expert panel sessions with well-known KOLs
- Executed LinkedIn Live open forum, featuring topics discussed in white paper
- Conducted ongoing media relations and corporate visibility/awareness – specifically throughout the U.S. launch of Hadlima
The Change We Delivered

- Elevation among key stakeholders from FDA officials to key opinion leaders of Samsung’s emerging leadership in the public discourse on the value of biosimilars through the expert panel series, White Paper and two successful open forums
- Closed expert panels consisted of 17 biosimilar influencers and decision makers from a variety of organizations, including the FDA, American Cancer Research Foundation, Cleveland Clinic, Boston Medical Center and more
- 590 registrations for open forum event, exceeding goal of 300
- 1,200+ total views after event aired live
- Media coverage ongoing including STAT Opinion
Elevating Biosimilar Thought Leadership

Samsung Bioepis Sees Information Driving Utilization
Quarterly US Report Offers Detailed Information To Help Drive Biosimilar Uptake

Biosimilar makers split strategies in bid to take on top-selling Humira

Biosimilar makers split strategies in bid to take on top-selling Humira

Organon and Samsung Bioepis launch Humira biosimilar Hadlima in the U.S.

BioSpace

HCP Live

BioWorld

Managed Healthcare Executive

Savvy Pricing Practices Enabling Deep Discounts For Adalimumab And Gardigence

Generics Bulletin

Interview with Dr. Gillian Woollett, VP, Head of Regulatory Strategy and Policy at Samsung Bioepis – Xtalks Life Science Podcast Ep. 110

AJMC Biosimilars

Samsung Bioepis Report Correlates Biosimilar Pricing Changes With Market Adoption

PharmaVoice

MarketWatch

SAMSUNG BIOEPIS

BIOPHARMADIVE

Clarivate

The BioWorld Insider

LaVoeHealthScience
Elevating Biosimilar Thought Leadership

What’s the Hold-Up? Overcoming Barriers to the Use of Biosimilars

Panelists Explore What Exactly Is Holding Up US Adoption of Biosimilars

AjMC

SAMSUNG BIOEPIS

Improving Understanding and Acceptance of Biosimilars in the United States

White Paper, November 2021

Pharmacy Times

Build a Successful Biosimilar Adoption Plan

Many Health Care Systems Use These Products to Provide Similar but Cheaper Clinical Outcomes

LaVoieHealthScience
Questions?
Case Study 3: Issues Management Proactive Planning on New Product Entrant

Situation Analysis

• Outlook Therapeutics is developing a new product entrant in a multi-billion market for which there is a product used off-label
• Outlook Therapeutics will do development and regulatory work in order to file for commercial use of product in category
• Hence, Outlook Therapeutics product would be the first approved product based on the same base drug to gain approval in this category
• Patients at potential harm from “off-label use” with product from compounding pharmacy
Case Study 3: Issues Management Proactive Planning on New Product Entrant

Action Plan:

• Identify and develop content on the key issues, audiences and arguments
  • Pricing, reimbursement, reliance on partners, perception
• Monitor competitive intelligence
• Holding statements written in advance
• Confirm and agree on media relations and stakeholder communications goals and execution
• Establish communications channels and plan
The Change They Wanted

- Go from “stealth mode” during early development of its wet AMD drug to shaping the market and executing a pre-commercialization program with flexible, sophisticated and nuanced communications support

- Increase visibility by strategizing and executing optimal ways to reach the retina/ophthalmology community, developing rigorous competitive intelligence on potential competitors, and creating a 5-year commercialization plan
What We Did

✓ Refined ways to convey drug’s value while deflecting potential opposition on biosimilar and innovator drugs. Used marketing intelligence to inform the podium data presentations and 5-year commercialization plan.

✓ Identified and targeted influencers for KOL corporate and Phase 3 data briefings.

✓ Engaged relationships with key industry associations to boost Outlook’s footprint in retina and ophthalmology.

✓ Upgraded the Company’s LinkedIn profile and initiated a robust Twitter presence, including mini video posts.

✓ Developed key relationships with targeted ophthalmology and retinal trade reporters as well as industry.
The Change We Delivered

• Guided the central messaging and informed BOD action with competitive intelligence and gained the retina community’s acceptance of the drug
• Collaborated on podium presentations that showcased Phase 3 data, and helped created the 5-year direction and plan for the product launch
• Engaged with the retina community via trade press, podcasts, broadcast, speaker opportunities and social media
• Increased social media year over year - Twitter - 114% and LinkedIn - 9.5%, 2022 vs. 2021
• Prepared the company for various scenarios for FDA outcomes
• Highlighting public health risk of compounded use of Avastin
From 0 to 60: Market Positioning for Surprise Entrant in Retina Therapy

Outlook Therapeutics Announces Initiation of Open-Label Safety Study of Lytenava for Wet AMD

Outlook Therapeutics announced the initiation and enrollment of the first patients in its planned supplemental open-label safety study evaluating ONS-5010/Lytenava (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (AMD) (NORSE THREE).

BENZINGA
Outlook Therapeutics' Bevacizumab-vikg Shows Favorable Safety Profile In Retinal Disease Study

Outlook is positive with new chief executive at the helm

The Outlook on Getting Regulatory-Approved Bevacizumab to Market

Positive topline data for bevacizumab-vikg for retinal indications

Outlook Therapeutics announced topline results from its NORSE THREE open-label safety study of ONS-5010/Lytenava (bevacizumab-vikg) for retinal diseases. There were no unexpected safety trends, and the safety profile was consistent with prior data on bevacizumab for ophthalmic conditions, according to a press release from the company. Adverse events occurred in 10% of eyes, most commonly associated with the injection procedure and not the drug itself. No serious adverse events occurred, and the press release noted zero cases of ocular inflammation. Patients enrolled in this study had a range of retinal diseases, such as wet AMD, DME, and BRVO. Some patients received previous anti-VEGF treatment, with several patients previously receiving aflibercept (EYLEA) and ranibizumab (Lucentis). Later this year under the PHS Act.

Outlook Therapeutics' bevacizumab-vikg for wet AMD has experts anticipating Phase III success, but biased design likely to limit uptake

CLINICAL TRIALS ARENA

Despite Tepid Wall Street Response, Outlook Therapeutics Still Betting on Ophthalmic Bevacizumab Formulation | Ophthalmology Innovation Summit

Big4Bio

Spotlight Q&A: Outlook Therapeutics — Developing First Ophthalmic Formulation of Bevacizumab for FDA Approval

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“We continue to believe in the **public health need** to provide the retina community with an FDA-approved bevacizumab treatment option for wet AMD. We will request a formal meeting as soon as possible with the FDA to further understand the BLA deficiencies and how best to resolve them. Following this meeting with the FDA, the Company will be able to discuss next steps and the expected timing for resolution,” said **Russell Trenary**, President and CEO of **Outlook Therapeutics**.
Measurement Is Not Easy: How Do We Tell If It’s Working?

- Monitoring and environment scanning
  - Competitive Intelligence
  - Political environment
  - Analyst reporting and stock reaction (price and volume)
  - Media monitoring and sentiment
  - Influencer posts
- Adjust messaging based on recapping activities and feedback
- Retool story accordingly
Summary

• Begin early as your management team will allow
• Allocate budget and experienced services to partner with you
• Show management ROI starting immediately throughout the program
• Test impact and re-adjust along the way
• Expect competitive noise and be prepared to watch competitive threats
• Be patient, marketing and science/clinical team need to partner for success
Questions?
Thank you!

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