LaVoie Health Science
Strategic Communications

Market Shaping for New Categories in Advance of Approval

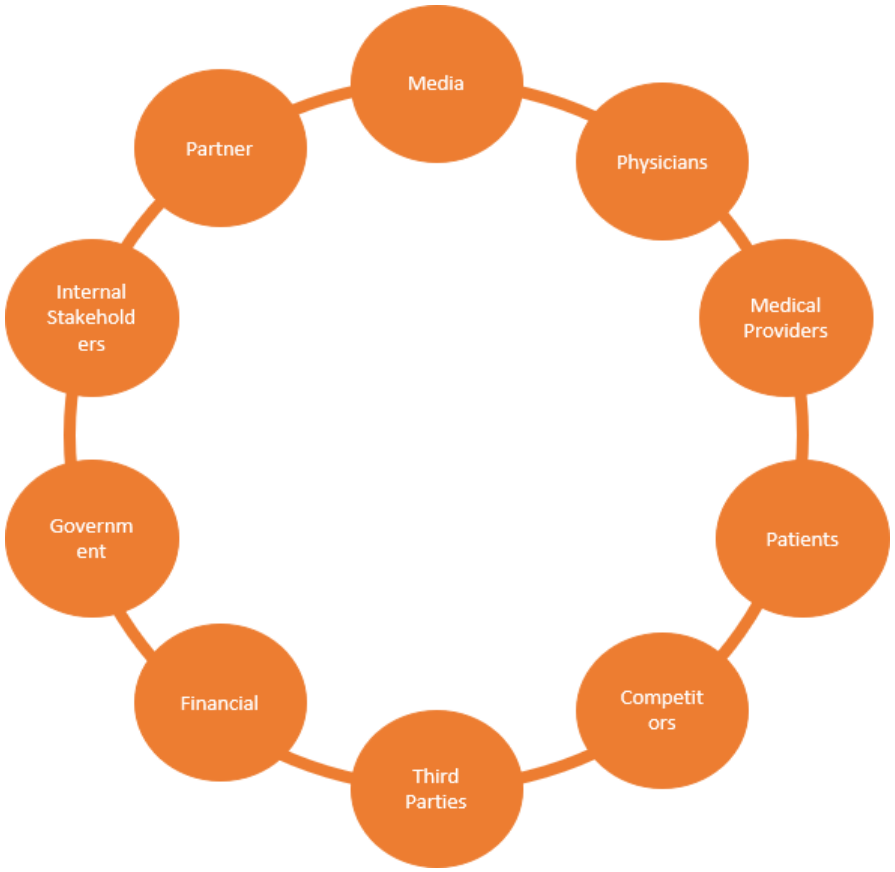
Donna L. LaVoie, CEO

September 19, 2023 – Webinar
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

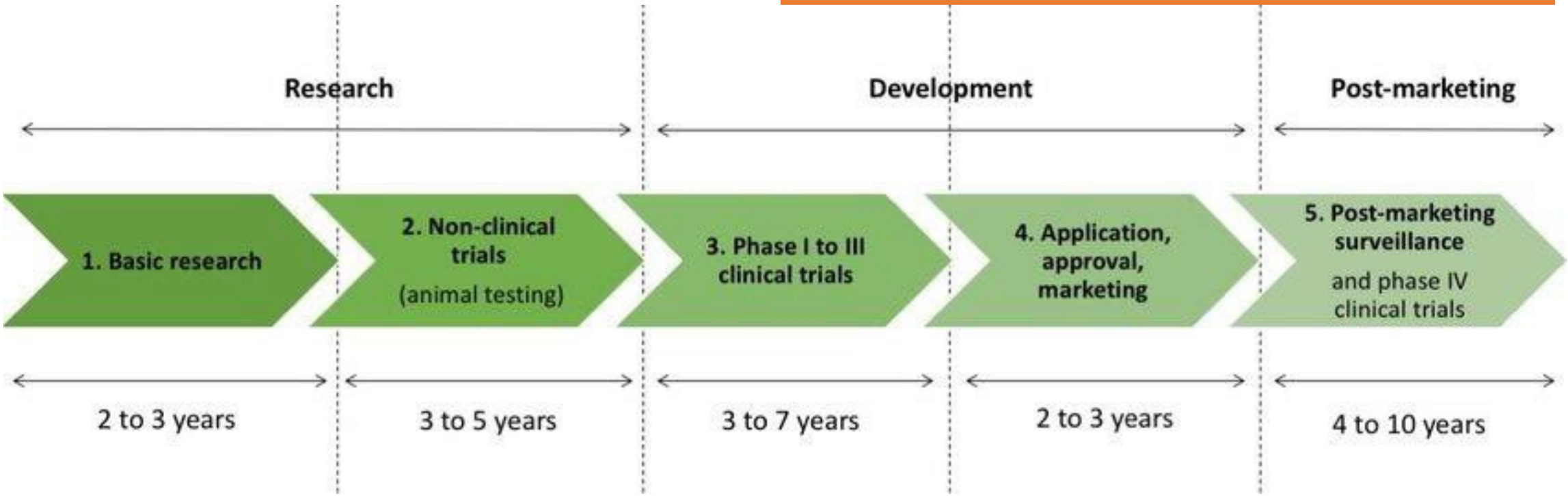
Key Audiences to Consider for Market Shaping



- 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)

Perception from Major Oncology Conference Media Reporting

September 07, 2022

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

FIERCE Pharma

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

By **Kevin Dunleavy** • Jan 30, 2023 11:01am

"The last endocrine therapy approved was about 20 years ago and effective endocrine options for this patient population are needed," Aditya Bardia, M.D., director of breast cancer research at Mass General Cancer Center and the principal investigator in the EMERALD trial, which supported the approval, said in a release.

- ✓ 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

MedCity News

…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 group

Stemline® A Menarini Group Company

FIERCE Pharma

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BREASTCANCER·ORG About you Learn Community

Research News

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.

EVERYDAY HEALTH

New Hormonal Treatment Orserdu Approved for Metastatic Breast Cancer

The therapy targets tumors with ESR1 mutations, significantly delaying cancer progression and death.

Medical Xpress

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

MedCity News

Where Big Pharmas Faltered, Stemline Succeeds and Lands FDA Nod in Breast Cancer

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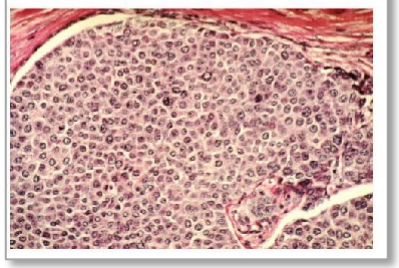


OncLive

FDA Approves Elacestrant for ER+/HER2–, ESR1-Mutated Advanced or Metastatic Breast Cancer

cure

Orserdu Approval for Metastatic Breast Cancer Represents 'Big Breakthrough'

FirstWord PHARMA

Top Story

FDA approves Stemline's oral SERD for ESR1-mutated breast cancer

Healio

FDA approves elacestrant for advanced breast cancer

PHARMACY PRACTICE NEWS

Orserdu Approved for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer

Pharmacy Times

Targeted Oncology

BIOCENTURY

formulary watch

ecancer

Supporting oncology professionals through education

The ASCO Post

Questions?

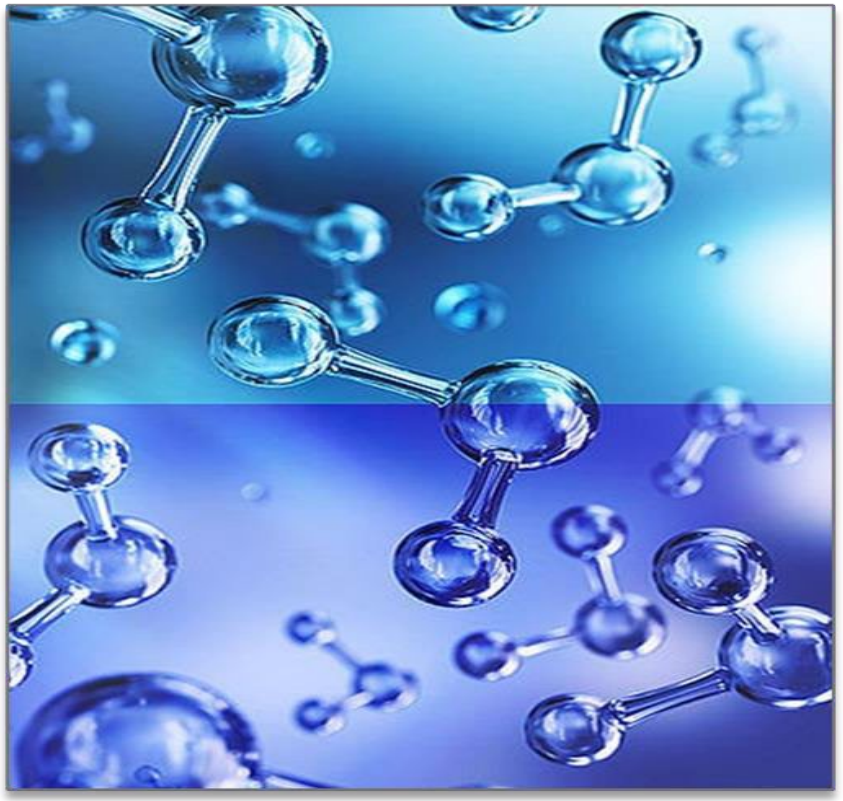
Case Study 2: Building Acceptance of Biosimilars

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 Bioepsis 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

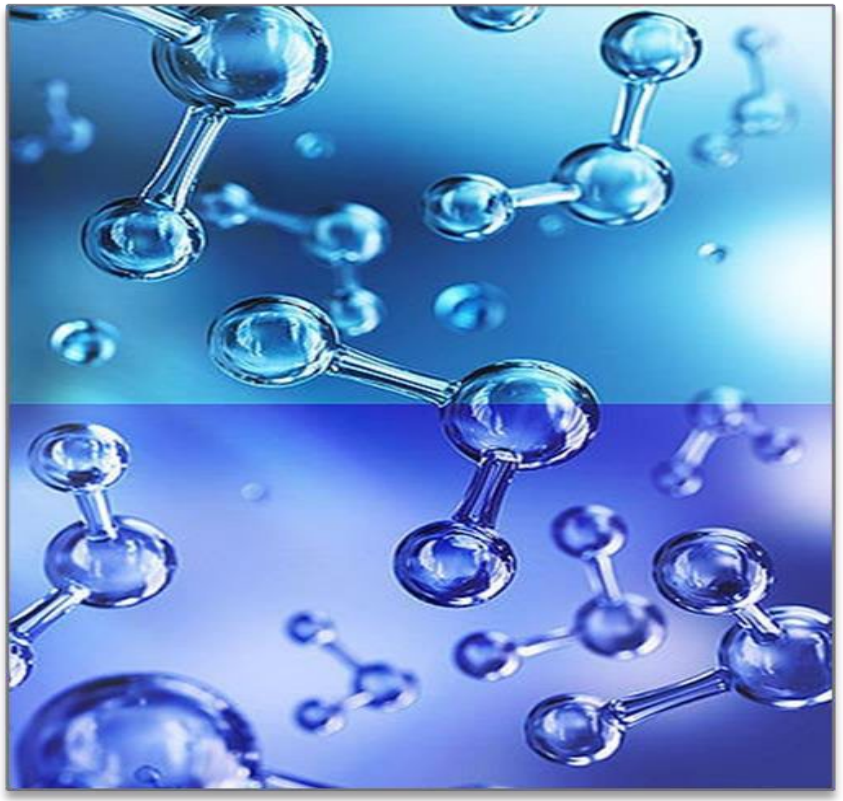
The Change They Wanted

- ✓ 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

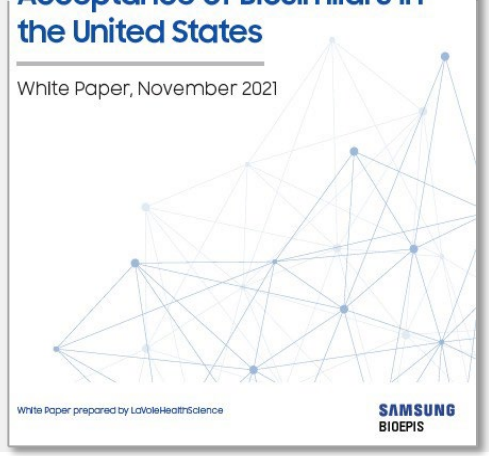


What We Did

- ✓ 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

Last Updated: August 22, 2023

SAMSUNG BIOEPIS

Samsung Bioepis Sees Information Driving Utilization

Quarterly US Report Offers Detailed Information To Help Drive Biosimilar Uptake

03 Jul 2023 | INTERVIEWS

by David Wallace

@Genericbulletin | david.wallace@citeline.com

STAT+ | LaVoieHealthScience

Removing barriers to biosimilar adoption in the United States

BioSpace

Ahead of Celltrion are **Organon** and Korean partner **Samsung Bioepis**, which Saturday **launched Hadlima** (adalimumab-bwwd) in the U.S. Hadlima has a sale price of $1,038 for a carton containing two pre-filled pens or syringes. According to the companies, this is an 85% discount compared to Humira's list price.

BIOPHARMA DIVE

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

BioWorld™

Engines revving for the US Humira biosimilar race

June 28, 2023 By Mari Serebrov No Comments

With the biggest biosimilar launch in the U.S. just days away, Humira's (adalimumab) record-breaking ride is quickly slowing down, but the Abbvie Inc. mega-blockbuster immunology drug is nowhere near the end of its road. Meanwhile, the U.S. journey is just beginning for the eight adalimumab biosimilars that could come to market as early as July 1 through licensing agreements with Abbvie. Besides revving their engines against Humira, the new launches will be looking to overtake Amgen Inc.'s biosimilar, Amjevita, which got a five-month headstart in the U.S., thanks to the first-mover status Amgen earned for being the first to sign a licensing agreement with Abbvie.

HCPLive®

Organon and Samsung Bioepis announced the United States (US) launch of the adalimumab biosimilar, adalimumab-bwwd (HADLIMA), on July 1, 2023. The tumor necrosis factor inhibitor (TNF) is used to treat patients with chronic autoimmune diseases including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, ulcerative colitis, and Crohn's disease.[1]

Advertisement

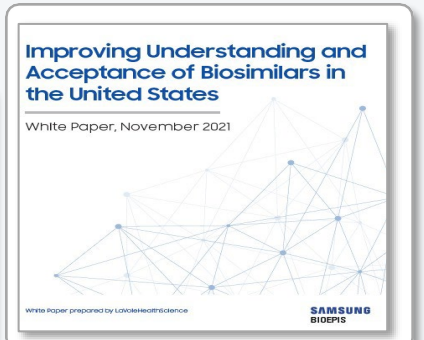
8 Humira Biosimilars Are on the Market

Managed Healthcare EXECUTIVE

Jul 4, 2023

Peter Wehrwein, Managing Editor

In addition to Fresenius Kabi's Idacio (adalimumab-aacf) and Biocon Biologics' Hulio (adalimumab-fkjp), the five other Humira's launched in July are Boehringer Ingelheim's Cyltezo (adalimumab-adbm), Organon and Samsung Bioepis' Hadlima (adalimumab-bwwd), Sandoz's Hyrimoz (adalimumab-adaz), Celltrion Healthcare's Yuflyma (adalimumab-aaty) and Coherus Biosimilar's Yusimry (adalimumab-aqvh).



MPR MEDICAL PROFESSIONALS REFERENCE

Several Biosimilars to Humira Now Available, Including an Interchangeable Product

Brian Park, PharmD | July 5, 2023

GENERICS BULLETIN

CITELINE COMMERCIAL

Savvy Pricing Practices Enabling Deep Discounts For Adalimumab And Glargine

Samsung Bioepis's Second Quarterly Biosimilar Report Provides Insight

Five Adalimumab Biosimilars Now Available in US Market

Jul 5, 2023

Lauren Biscaldi, Managing Editor

Article

Managed Healthcare EXECUTIVE

These medications join adalimumab-atto, which launched on January 31.

July 1 marked the launch of 5 different adalimumab (Humira) biosimilars, setting off the first round of therapeutic alternatives into the market, including adalimumab-abdm (Cyltezo), adalimumab-aqvh (Yusimry), adalimumab-bwwd (Hadlima), adalimumab-adaz (Hyrimoz), and adalimumab-fkjp (Hulio). These medications join adalimumab-atto (Amjevita), the first adalimumab biosimilar that launched on January 31, 2023.[1]

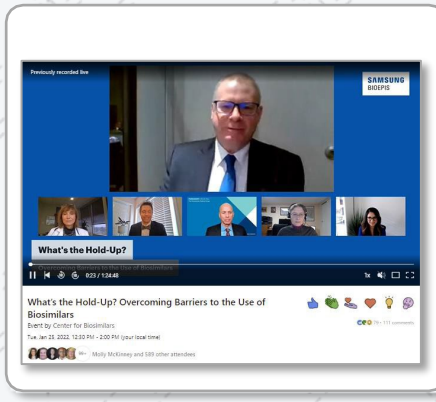
Interview with Dr. Gillian Woollett, VP, Head of Regulatory Strategy and Policy at Samsung Bioepis – Xtalks Life Science Podcast Ep. 110

Posted on: May 18, 2023 in Blogs | Life Science Podcast | Life Science Blogs

By: Sarah Hand, M.Sc.

Sarah and Dr. Woollett also discuss Samsung Bioepis' first US Biosimilar Market Report (linked below) and some of its key findings on biosimilar cost savings, uptake and market share. She also shares the way forward to help biosimilars see broader use both in the US and Europe.

Xtalks



AJMC | THE JOURNAL FOR BIOSIMILARS

Samsung Bioepis Report Correlates Biosimilar Pricing Changes With Market Adoption

May 10, 2023

Skylar Jeremias

PharmaVoice

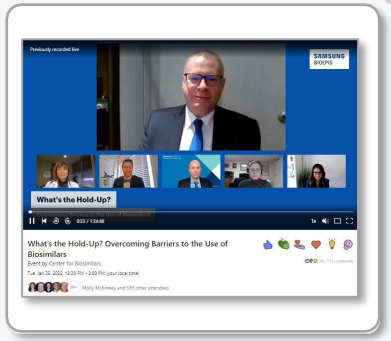
Biosimilar makers split strategies in bid to take on top-selling Humira

MarketWatch

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

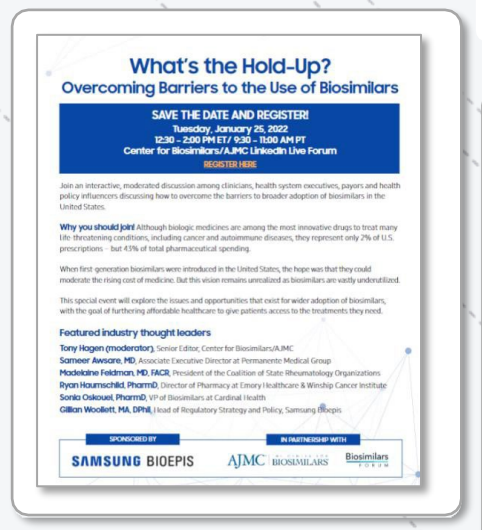
Elevating Biosimilar Thought Leadership

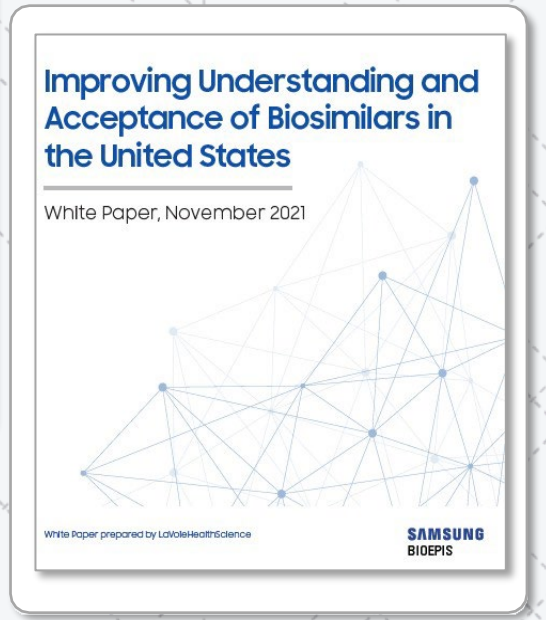
SAMSUNG BIOEPIS

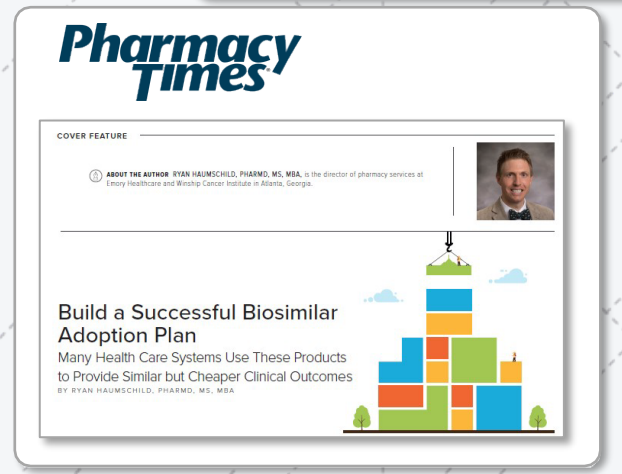


STAT+ | LaVoieHealthScience

Removing barriers to biosimilar adoption in the United States







Questions?

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

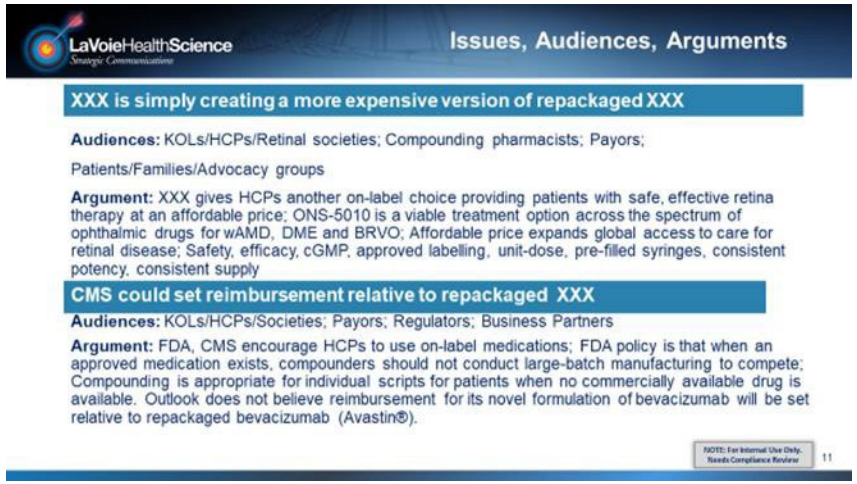
Situation Analysis

- 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

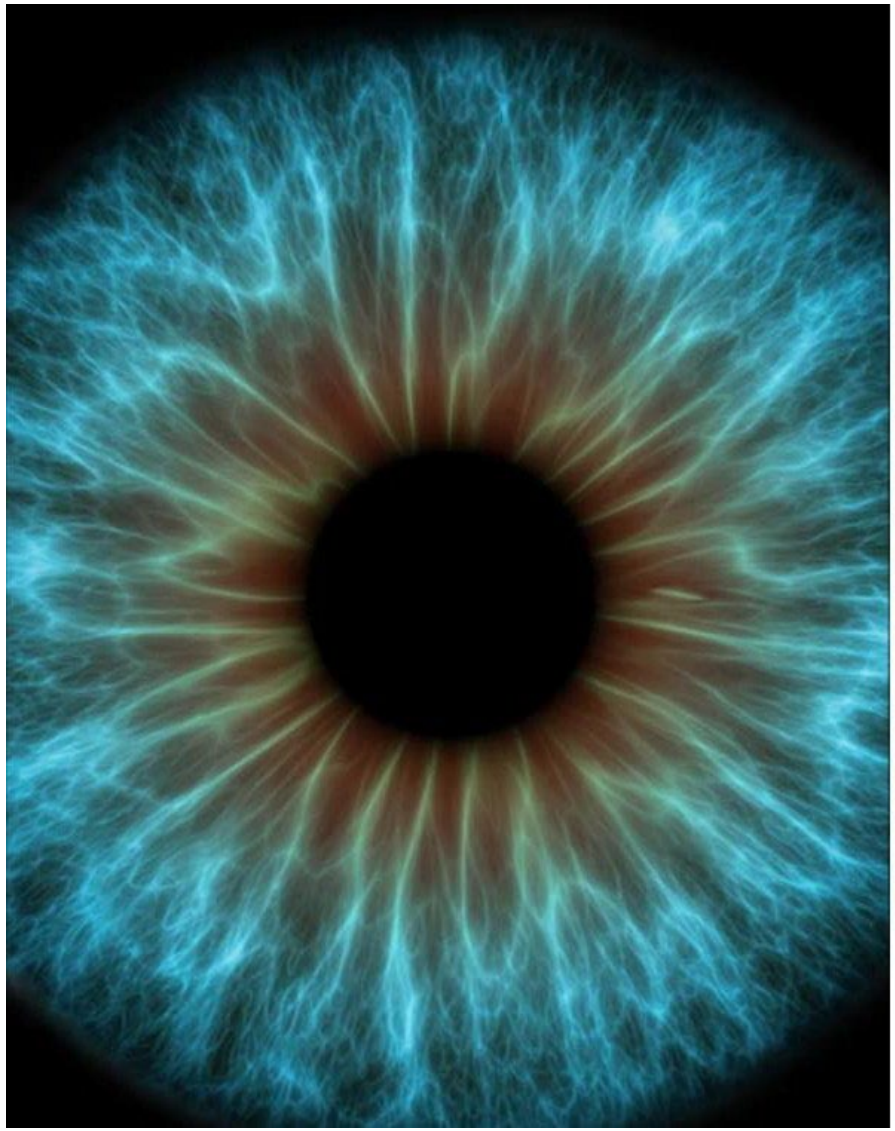
Action Plan:

- 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



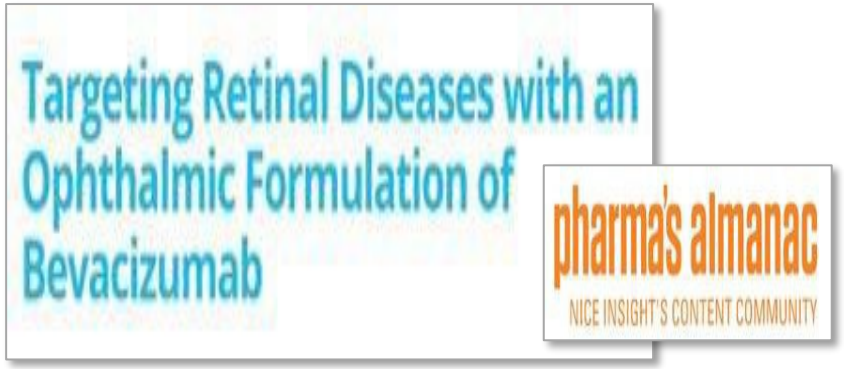
The Change They Wanted

- 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

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

OUTLOOK THERAPEUTICS | eyewire NEWS

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).

Company seeks first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications

July 8, 2020
David Hutton

Modern Retina | Ophthalmology Times

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

CLINICAL TRIALS ARENA

Targeting Retinal Diseases with an Ophthalmic Formulation of Bevacizumab

pharma's almanac
NICE INSIGHT'S CONTENT COMMUNITY

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

OIS

BENZINGA

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

Outlook is positive with new chief executive at the helm

08-07-2021

thepharmaletter
Up to date news for the Pharmaceutical and Biotechnology industries

The Outlook on Getting Regulatory-Approved Bevacizumab to Market

LISTEN NOW

OIS

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 were treatment naive and others had previously received an
MD is successful, Outlook Therapeuti
later this year under the PHSA 351(a) regu

ASCRS EYEWORLD

Big4Bio

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

OCTOBER 26, 2020

LaVoieHealthScience Client Spotlight

Following is a Q&A with Lawrence Kenyon, President, CEO and CFO of **Outlook Therapeutics (NASDAQ: OTLK)**, a late-stage clinical biotech company focused on developing the first FDA-approved ophthalmic formulation of bevacizumab-vikg to treat wet age-related macular degeneration (wet AMD) and other retinal diseases. By way of background for our readers, age-related macular degeneration, AMD, is a common eye

“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 Its 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!

Donna L. LaVoie

President & CEO

LaVoieHealthScience

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