

Aurinia's Lupkynis Gaining Traction and Generating High Interest

Companies: AUPH, AZN, GSK

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Research Question:

Are Aurinia's Lupkynis and GSK's Benlysta for the treatment of LN gaining traction? Are they challenging the standard of care? Is one performing better than the other? Is there a place for both?

Summary of Findings

- In this update to [Blueshift's July 29 report](#), sources found that Aurinia Pharmaceuticals Inc.'s (AUPH) Lupkynis is outperforming GlaxoSmithKline PLC's (GSK) Benlysta by generating more interest and excitement. However, there is a place for both drugs and, according to these primary and secondary sources, they are both already challenging the standard of care.
- Two sales professionals, one selling Lupkynis and one selling AstraZeneca PLC's (AZN) recently approved [Saphnelo](#) for the treatment of systemic lupus erythematosus (SLE), both said Lupkynis is generating high interest levels in the lupus nephritis (LN) treatment community.
- The Lupkynis sales professional said, unlike three months ago, they now are receiving requests from hospitals to visit and present on the drug. The AstraZeneca rep said the rheumatologists they call on are asking questions about how Lupkynis interacts with Saphnelo, but there is no interest in or questions about Benlysta. The third source, a rheumatologist, said Lupkynis will be adopted in academic settings with lupus clinics, while Benlysta is considered an expensive [plaquenil](#).
- Two secondary sources featuring medical professionals discussing Benlysta and Lupkynis stressed that the medical community is learning how to use both drugs and there are positives for each. One physician said, "I personally would choose voclosporin (Lupkynis) if I had a patient who was spilling very high amounts of protein, because it tends to work more quickly and it gets directly at the protein part of the clinical effects of lupus nephritis. On the other hand, if I had a patient who had a lot of active arthritis and rashes along with their lupus nephritis, I would probably pick Benlysta first." Another physician said, "I think these two drugs show us the possibility that we might use them together and get rid of the older drugs, and really minimize the older drugs and then use them on a longer-term basis to preserve kidney function, as well as keep the lupus in check."

Background

Blueshift Research's [July 29 report](#) on Aurinia's [Lupkynis](#) and GSK's [Benlysta](#), the first drugs approved specifically for the treatment of lupus nephritis (LN), found that there is room in the market for both drugs and over the next two to three years these drugs would become the standard of care.

With the almost simultaneous launch of each drug, Blueshift Research contacted a few sources to determine if either or both drugs were gaining traction and challenging the standard of care.

Current Research

Blueshift Research assessed whether Aurinia's Lupkynis and GSK's Benlysta for the treatment of LN are gaining traction and challenging the standard of care, as well as whether one is performing better than the other or if there is room for both. We employed our pattern mining approach to establish two independent silos, comprising three primary sources (all repeat sources from the July 29 report), and two secondary sources focused on both Lupkynis and Benlysta. Interviews were conducted September 15-22.

- 1) AUPH and AZN Sales Professionals and the Founder of a Lupus Foundation (3)
- 2) Secondary sources (2)

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Silos

1) AUPH and AZN Sales Professionals and a Founder of a Lupus Foundation

These three repeat sources see both Lupkynis and Benlysta eventually becoming the standard of care for the treatment of LN. Lupkynis is generating the most interest and excitement especially within the nephrology specialty. The sales professionals noted that Benlysta, which has been available since its approval in March 2011 for the treatment of systemic lupus erythematosus (SLE) and received the expanded indication for LN in December 2020, is not generating any questions from physicians they call on. Nor have not encountered any GSK reps promoting it. Both believe Lupkynis is outperforming Benlysta. The COVID-19 pandemic is still negatively affecting the launch of both drugs as one source said 25% of physicians will not meet face-to-face.

Key Silo Findings

Are Lupkynis and Benlysta gaining traction in the treatment of LN?

- 2 said Lupkynis and Benlysta are gaining traction in treating LN and both think Lupkynis is generating the most excitement and interest.
- 1 said Lupkynis will gain traction in academic centers with lupus clinics.

Are Lupkynis and Benlysta challenging the standard of care?

- 3 expect both drugs to become part of the standard treatment for LN.

Is one drug outperforming the other?

- 2 implied that Lupkynis is outperforming Benlysta.
- 1 said Benlysta is considered expensive.

Will there be a place for both Lupkynis and Benlysta?

- The general opinion is that there will be a place for both Lupkynis and Benlysta in treating LN.

1) Aurinia immunology specialist in the Northeast in this therapeutic class for more than 10 years; repeat source

Unlike three months ago, this Aurinia rep said the adoption of Lupkynis for the treatment of LN is gaining traction and hospitals are beginning to solicit visits to present on the drug. The company has reported over 800 Lupkynis start forms as of August 5 despite the challenges of many hospitals and practices prohibiting face-to-face sales calls. This rep has not seen a Benlysta rep or heard any comments about the drug on their sales calls. This source said Lupkynis is outperforming Benlysta, and they expect it is challenging the standard of care, especially among nephrologists.

Are Lupkynis and Benlysta gaining traction in the treatment of LN?

- "Benlysta – not that I'm aware of. Haven't seen a GSK rep or comments in offices. Lupkynis – we have about 800 patient start forms – this is getting traction. Can't say how many patients there are nationally. Company feels we are doing well."
- "I'm getting calls now to come into hospitals to present on Lupkynis – I didn't get any unsolicited calls three months ago. I do believe this will reach \$500 million in three years."
- "Covid is still a factor – 25% of doctors won't meet face-to-face. Makes it difficult to get the word out to the audience I need to reach."

Are Lupkynis and Benlysta challenging the standard of care?

- "Yes, Lupkynis is challenging the standard of care. Nephrologists believe that this will be the standard of care in a few years as they are getting more experience and realize the benefits we talked about before."

Is one drug outperforming the other?

- "Yes, Lupkynis is. Nephrologist almost never ask about Benlysta. I never see Benlysta reps in the nephrology office."

Will there be a place for both Lupkynis and Benlysta?

- "Based on Benlysta performance to date, there will be a minority business for Benlysta. Rheums are familiar with it, rheums prefer the IV form and it's not a calcineurin inhibitor (which they are less familiar with). Some nephrologists –

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the older ones for sure – are hesitant to use calcineurin inhibitors due to the legacy cni's and problem with nephrotoxicity. With the legacy products – cyclosporin and tacrolimus – they were used primarily in transplant patients and the nephs were called in to mitigate the side effect problems they caused.”

Summary of interview from July 29 report: This sales professional has experienced resistance in physician access due to COVID-19 and in physician prescribing adoption in the first six months of promotion. There is little interest in prescribing Benlysta or Lupkynis for LN. Nephrologists and rheumatologist are well aware of the Lupkynis data but broader adoption in prescribing for LN patients will take another 18 months. Neither drug is currently disrupting the standard of care. Doctors do not have a sense of urgency to use the new drugs in LN. Benlysta has no path forward—it is only used in patients who cannot tolerate all other options. Lupkynis can be part of a new standard of care—a triple therapy with steroids and immunosuppressants—and could reach sales of \$500 million in three years. The source's most influential rheumatologist states, “What's on the market now works. The number of patients diagnosed with LN is small and reasonably controlled.” Aurinia's job is to create a sense of urgency for LN patient use. Roche/Genentech have a CD20 pathway drug coming—a pathway similar to Rituxan—which is well known with these healthcare professionals.

2) Immunology specialist in Florida; former Aurinia sales professional selling new drug from AZN; repeat source

Lupkynis is getting more traction and becoming a bigger part of the standard of care as healthcare professionals gain clinical experience with the drug and see the faster action and ability to use lower doses of corticosteroids. More physicians in the offices he calls on are asking about how the new AZN drug interacts with Lupkynis but almost never ask similar questions about Benlysta. For lupus nephritis, nephrologists are calling the shots and getting more receptive to treating with Lupkynis. There is a lot of hype for Lupkynis in the rheumatologist's offices and very little for Benlysta. There is room for both LN drugs but the winner at this time looks to be Lupkynis.

Are Lupkynis and Benlysta gaining traction in the treatment of LN?

- “I think Lupkynis has been gaining traction. More physicians are asking about using Lupkynis and using it together with AZ's new drug. Regarding Benlysta, I have not been asked or heard anything from physicians about Benlysta nor seen reps promoting it in the field.”

Are Lupkynis and Benlysta challenging the standard of care?

- “Yes, I believe they are. They are increasing market share. Physicians needed to get the experience. Nephrologists are very receptive to the lower steroid dose and the faster onset of action and are favoring Lupkynis. Rheums do not use the higher doses of steroids – more of a nephrologist behavior – so that is not so important to them. Nephrologists are still calling the shots for LN and are the decision makers. Rheums are not the decision makers and let the nephs call it – the 2 grams of protein spilling into the urine is their limit – turn it over to the nephs.”

Is one drug outperforming the other?

- “Lupkynis is outperforming [others]. I'm hearing more hype about Lupkynis than Benlysta in the rheum offices I call on. Benlysta just doesn't seem to be front of mind in either specialty.”

Will there be a place for both Lupkynis and Benlysta?

- “Yes, there will be. Still, lots of patients are treated with Benlysta for SLE and LN. But no real hype or excitement, but both drugs are being used but Lupkynis is the one getting more of the new patients.”

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*Immunology specialist in Florida;
former Aurinia sales professional
selling new drug from AZN*

Summary of interview from July 29 report: There is excitement within the patient and treatment communities for both new drugs. This source projects Lupkynis to be the superior drug of the two but thinks it will take a long time before it is the standard of care. Lupkynis has major advantages over Benlysta in tapering the steroid dose and much quicker timing for a complete response (two years vs. one). Oral administration is extremely important to the younger patient community. Nephrologists will tell you that Benlysta is not a great drug and they are more comfortable with the calcineurin pathway of Lupkynis. As LN is a rare disease, this source does not believe there will be dramatic share shifts. He hears that Roche will be the next entrant with a new drug for LN.

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3) Rheumatologist at a private clinic in California; repeat source

Lupkynis can gain traction in academic hospitals that sponsor lupus clinics.

Are Aurinia's Lupkynis and GSK's Benlysta for the treatment of LN gaining traction, and challenging the standard of care? Is one performing better than the other or is there a place for both?

- "In academic centers, Benlysta is still generally considered an expensive [plaquenil](#) to my knowledge. I do consider it in private practice as we deal with mucocutaneous lupus more."
- "After reading more about Lupkynis, it seems perfect for academics and nephrologists dealing with lupus nephritis. In such a setting, I used to use tacrolimus and cyclosporin for those cases. So, I do think it can get traction in academic institutions where they have lupus nephritis clinics."

Summary of interview from July 29 report: Existing therapies for lupus nephritis include cyclophosphamide, CellCept (with and without tacrolimus), and rituximab. Although the studies are not robust, Benlysta is the drug of choice due to a high frequency of elevated liver enzymes in the U.S. population. Academic centers use it in moderately active lupus (with CellCept). Because LN patients typically present with cognitive issues, infusion helps ensure compliance. Rheumatologists sometimes refer to Benlysta as "expensive Plaquenil" due to the limited change in disease activity, so it is unlikely to achieve blockbuster status. This source had not heard of Lupkynis; there have been no studies presented at the American College of Rheumatologists (ACR) to his knowledge. To raise awareness, Aurinia will need to host lectures and present data through the ACR.

Secondary Sources

These two secondary sources focused on physicians' discussions regarding the merits and use cases for both Lupkynis and Benlysta.

Aug. 19 Medscape [article](#)

Physicians discuss the merits of both voclosporin (Lupkynis) and belimumab (Benlysta) and suggest that they may be used in combination and replace the old drugs used to treat LN.

- "With the approval by the US Food and Drug Administration of the calcineurin inhibitor voclosporin (Lupkynis) in January and belimumab (Benlysta) a month before that, clinicians now have new options for treating lupus nephritis in combination with a background immunosuppressive agent, such as mycophenolate mofetil."
- "But which combination should clinicians choose?"
- "Brad Rovin, MD, a nephrologist with the Ohio State University Wexner Medical Center, Columbus, Ohio, who worked on the phase 3 voclosporin trial, pointed to that drug's fast reduction in proteinuria in a session of the Pan American League of Associations for Rheumatology (PANLAR) 2021 Annual Meeting. That effect on proteinuria is likely due to its effect on podocytes, special epithelial cells that cover the outside of capillaries in the kidney, he said."
- "The way I think about it now is, what else do these drugs add? And this idea of preserving the histology of the kidney is really important, and this can be done with voclosporin," Rovin said."
- "Belimumab is also hailed as an effective tool, particularly for the prevention of flares. In the trial leading to its approval, just under 16% of patients experienced a renal-related event or death over 2 years, compared with 28% of the group that received placebo. Those receiving belimumab had a 50% greater chance of reaching the primary efficacy renal response, which was defined as a ratio of urinary protein to creatinine of 0.7 or less, an estimated glomerular filtration rate that was no worse than 20% below the pre-flare value or at least 60 mL/min/1.73 m², and no use of rescue therapy for treatment failure."
- "The endpoints in the belimumab lupus nephritis trial were 'quite rigorous,' Richard A. Furie, MD, said in the same session at the meeting. Patients with class V lupus nephritis were included in the trial, although disease of this severity is known to be particularly difficult to treat, he noted."

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- “There's little question that our patients with lupus nephritis will benefit from such a therapeutic approach' with belimumab and mycophenolate, said Furie, professor of medicine at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, in Hempstead, New York. 'But regardless of which combination clinicians use, we are making advances, and that means better outcomes for our patients with lupus and lupus nephritis.’”
- “Graciela Alarcon, MD, MPH, professor emeritus of medicine at the University of Alabama at Birmingham, who moderated the discussion, said there is no sure answer regarding the best choice for clinicians.”
- “A's long as there's no head-to-head comparison between the two new compounds, I don't think that the question can be answered,' she said.”
- “With voclosporin's protective effects and belimumab's flare prevention, the two could potentially be used together at some point, he suggested.”
- “Brad Rovin, MD, said, 'I think these two drugs show us the possibility that we might use them together and get rid of the older drugs, and really minimize the older drugs and then use them on a longer-term basis to preserve kidney function, as well as keep the lupus in check.’”

Aug. 24 The American Journal of Managed Care [episode](#)

German Hernandez, MD, FASN, FACP, and Ellen Ginzler, MD, MPH, provide insight into the FDA approved therapies for lupus nephritis, belimumab and voclosporin, including an overview of clinical evidence, mechanism of action, and patient selection. In conclusion Dr. Ginzler provides a case for the use of both Lupkynis and Benlysta.

- “Ellen Ginzler, MD, MPH: 'I personally would choose voclosporin if I had a patient who was spilling very high amounts of protein, because it tends to work more quickly and it gets directly at the protein part of the clinical effects of lupus nephritis. On the other hand, if I had a patient who had a lot of active arthritis and rashes along with their lupus nephritis, I would probably pick Benlysta first.’”

Additional research by James Boland and Pam Conboy.

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