PRESS RELEASE

SPIOMET4HEALTH

Polyendocrine Metabolic Ovarian Syndrome (PMOS) in adolescents and young women: towards a pathophysiology-guided treatment

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 899671

SPIOMET4HEALTH presents promising clinical results and sets the stage for the future of PMOS care

- The clinical trial involving 316 young women across Europe showed improvements in ovulation, menstrual regularity and key hormonal and metabolic markers.
- The Final Policy Event brought together researchers, patient organisations and European policymakers to discuss how scientific evidence can translate into better healthcare and stronger women's health policies.

The European project **SPIOMET4HEALTH has delivered promising clinical results and valuable insights for the future of Polyendocrine Metabolic Ovarian Syndrome (PMOS) care.** However, turning these achievements into real improvements will require **sustained funding, strong European collaboration and a shared commitment** to advancing patient-centred healthcare.

This was the clear message at the **SPIOMET4HEALTH Final Policy Event**, held on 6 November at the University of Bologna and online. Scientific experts, healthcare professionals and patient representatives came together to discuss the project's results and their implications for future clinical practice and health policies.

The event featured **contributions from Members of the European Parliament Sirpa Pietikäinen and Billy Kelleher**, bringing a European policy perspective to the discussions and reinforcing the relevance of the project's findings to wider priorities in women's health, research investment and equitable access to healthcare.

Since 2021, SPIOMET4HEALTH has investigated a **novel therapeutic approach targeting the underlying endocrine and metabolic causes of PMOS.** The project conducted a phase II clinical trial involving 316 young women across six countries: Spain, Italy, Austria, Norway, Denmark and Turkey. All participants received individualised support within a standardized lifestyle intervention programme.

The results showed encouraging outcomes among participants receiving SPIOMET, a low-dose combination of spironolactone, pioglitazone and metformin. **Ovulation and regular menstrual cycles were more frequent, while excessive body hair growth and acne decreased**. Blood androgen levels also declined in the SPIOMET group, while quality of life improved across all study groups. These findings represent key steps towards better PMOS care. As **Dr. Lourdes Ibáñez**, project coordinator at Hospital Sant Joan de Déu, stated:

"Our results bring new hope for women with PMOS: combining SPIOMET with lifestyle intervention could help us address the condition itself, not just its symptoms. This is an important step towards better care for millions of women."

Messages from those living with PMOS and fighting for better care

Carolina Bucalo, a PMOS patient who participated in the SPIOMET4HEALTH clinical trial, shared her personal experience during the event and called for **greater recognition of women's health concerns**:

"This experience taught me something very important: we don't have to accept our symptoms or suffer in silence. We deserve research that takes our health seriously."

Patient organisations played a central role in the event. Representatives from **SOPKEurope, PMOS Norge and the Young Women's Health Group** highlighted persistent challenges in diagnosis, access to information, research funding and equitable healthcare, while calling for greater patient involvement in clinical research. As **Martina Alberani**, from the Young Women's Health Group, emphasised:

"Patient involvement is not an optional extra. When patients are truly involved, research becomes stronger, healthcare becomes better, and more people have the opportunity to live healthier lives."

Recommendations for European policymakers

The project's achievements are clearly oriented to inform the future of women's healthcare in Europe. The discussions in Bologna addressed the barriers that limit progress in PMOS diagnosis and highlighted the need to translate scientific progress into concrete improvements in PMOS care. Key recommendations included:

- **Greater recognition of PMOS as a public health priority**, supported by improved awareness, early diagnosis, data collection and sustained research investment.
- **Meaningful patient participation**, ensuring that the experiences and priorities of patients influence clinical studies and healthcare decisions.
- **Continued support for clinical development**, allowing promising research findings to advance towards potential new treatment options.
- **Stronger European coordination** and long-term commitment to translating scientific evidence into accessible healthcare improvements.
- **Straightforward regulatory pathways** and greater consideration of women's health needs within European research and healthcare policies.
- **Securing sustained and dedicated funding** for women's health research, ensuring that promising scientific advances can translate into accessible treatments.

SPIOMET4HEALTH leaves behind an important scientific and collaborative legacy. The results provide a foundation for the potential next stage of development: a larger phase III clinical trial to further evaluate the efficacy and safety of SPIOMET.

Beyond its scientific achievements, SPIOMET4HEALTH has contributed to increasing awareness of PMOS, strengthening European collaboration and demonstrating the value of placing women's health at the centre of research and innovation.

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