I am Gabriella Giancane, a researcher in Paediatric Rheumatology at Gaslini Institute in Genoa, Italy, and I am proud to describe this study conducted on behalf of the Printo Organization.

Objective of the present study was to evaluate the long-term safety profile of anakinra in patients with systemic JIA in current clinical practice.

We extracted data from patients with systemic JIA treated with anakinra and enrolled in the Pharmachild registry before September 2018 and we retrospectively analysed them.

Primary end-points of the study were the occurrence of non-serious adverse events of at least moderate intensity and serious adverse events including macrophage activation syndrome (MAS).

We also analysed the duration of anakinra treatment and the reasons for discontinuation.

All endpoints were analysed overall, by different treatment sets and stratified by 6 month-time windows up to more than 24 months.

We enrolled 306 patients with systemic JIA out of more than 8000 patients in the Pharmachild registry and we divided them in three different treatment sets thus indicating those patients getting continuously anakinra for at least 12, 18 and 24 months.

The table depicts the main features of our complete set of patients and in the three different long-term treatment sets.

We found a total 201 adverse events in around one-third of our patients.

They were mostly represented by infections (26 percent), with an incidence rate of 10.2.

More interestingly, among immune system disorders, we found 12 events of haemophagocytic lymphocytosis that, according to the MedDRA dictionary which is used in the Pharmachild registry to classify the overall number of adverse events, can be considered as a synonym of MAS, with an incidence rate of 2.4.

The analysis of the three different long-term treatment sets revealed that there was no increasing frequency of adverse events by increasing the duration of treatment with anakinra.

About serious adverse events, we found 56 events in around 14 percent of our patients, again mostly represented by infections and followed by 11 events of MAS, with an incidence rate of 2.2.

The trend in the long-term treatment sets was overlapping with the previous analysis of the overall number of adverse events.
For each treatment set, more frequent adverse and serious adverse events occurred in the first 6 months of treatment then decreasing over time.

SLIDE 5

A second part of our study focused mainly on MAS.

Ten patients had already had a history of MAS at baseline, which means before starting anakinra treatment.

Twelve events occurred: eleven as a first occurrence and one as a second occurrence in our patients after anakinra start.

SLIDE 6

MAS during anakinra treatment regarded 11 events, which occurred mainly in the first 6 months of treatment with the biologic.

After anakinra discontinuation, we found 8 events of MAS, which occurred in particular in the first 6 months after anakinra discontinuation.

We could conclude that there was no increased risk for MAS, including no rebound effect, after anakinra discontinuation.

SLIDE 7

MAS was mainly triggered by disease flare, in one third of the cases, followed by treatment change and infections.

SLIDE 8

Finally, we analysed treatment discontinuation, which occurred in 76 of our patients and this was mainly due to inefficacy (almost 47 percent of our patients) and remission (in around 20 percent).

Adverse events of at least moderate and mild intensity caused discontinuation in a very low number of our patients.

SLIDE 9

In conclusion, long-term treatment with anakinra in sJIA patients was overall well tolerated.

Adverse events especially occurred in the first 6 months of treatment with the biologic and did not increase in case of long-term treatment with anakinra.

No increase in MAS could be observed either during anakinra treatment or after discontinuation.

SLIDE 10
I would like to thank you for your attention and if you are further interested in the whole body of this manuscript please visit the website of the Journal of Rheumatology. Thank you. Bye.