Here is a CTIS-compliant Results Summary (aligned with EU Clinical Trials Regulation requirements.

Summary of Results
CARBASTIR Study

Clinical Study of Stiripentol (Diacomit®)

The CARBASTIR study was an open-label, retrospective and prospective, single-center clinical study conducted in patients with pharmacoresistant focal epilepsy.

A total of 52 patients were included in the retrospective analysis, while 10 patients participated in the prospective pharmacokinetic part of the study. Given the limited sample size, the samples collected during the prospective phase were not processed or analyzed, as the resulting data would not have been sufficiently robust to support meaningful interpretation.

Among the 52 patients included in the study, 25 were female and 27 were male. The median age at first seizure was 2.0 years, and the median age at diagnosis was 2.2 years, indicating that the disease was generally recognized early. Most patients experienced focal seizures as their initial seizure type (70%), whereas generalized seizures occurred in 24% of cases. Structural etiologies were identified in most patients, with focal or extensive cortical dysplasia and ischemic lesions being the most frequently reported. Genetic etiologies were reported in seven patients and included tuberous sclerosis, ring chromosome syndromes, and mutations in genes such as FGF and KCNT1.
At baseline, focal seizures were the predominant seizure type, affecting 94% of patients. Histories of status epilepticus and seizure clusters were reported in approximately one-third of patients for whom data were available.

The median age at carbamazepine initiation was 4.0 years. In addition to carbamazepine, most patients were receiving other antiseizure medications, particularly benzodiazepines, vigabatrin, valproate, topiramate, and levetiracetam. The overall pattern of concomitant treatments remained stable throughout the study.

Stiripentol was initiated at a median age of 6.2 years and was associated with a progressive reduction in seizure frequency. Median monthly seizure frequency decreased over time, and these improvements were maintained during long-term follow-up. At the last available study visit, 67.7% of evaluable patients achieved at least a 50% reduction in seizure frequency, while 61.3% achieved a reduction of at least 75%. Furthermore, 35.5% of patients were seizure-free at their last assessment. Kaplan–Meier analyses also suggested sustained seizure control over time, with an estimated 67.1% probability of remaining seizure-free after three years of treatment.
In addition to reducing seizure frequency, the combination therapy was associated with reductions in the occurrence of *status epilepticus* and seizure clusters. These clinical improvements translated into lower healthcare resource utilization, including reduced use of rescue medications and fewer epilepsy-related emergency department visits and hospitalizations.

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Safety information was collected retrospectively from medical records, and all reported adverse events were considered adverse drug reactions. No new or unexpected adverse drug reactions related to stiripentol were identified. The safety profile observed was consistent with the known tolerability profile of stiripentol.
Importantly, no new safety concerns were identified in this population of patients with refractory focal epilepsy, despite the fact that stiripentol is currently approved for a different patient population, namely patients with Dravet syndrome.

In conclusion, although limited by its relatively small sample size and single-center design, this real-world study provides supportive evidence for the potential benefit of stiripentol as add-on therapy in patients with refractory focal epilepsy receiving carbamazepine.
Stiripentol treatment was associated with clinically meaningful reductions in seizure frequency, seizure clusters, *status epilepticus*, and epilepsy-related hospitalizations, while maintaining a safety profile consistent with the established safety profile of stiripentol.
These findings suggest that stiripentol may represent a valuable therapeutic option for selected patients with refractory focal epilepsy and support further evaluation in prospective, controlled studies with standardized efficacy and safety assessments.