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### FIVE-YEAR FINAL RESULTS OF A PHASE 3 STUDY OF CPX-351 VERSUS 7+3 IN OLDER ADULTS WITH NEWLY DIAGNOSED HIGH-RISK/SECONDARY ACUTE MYELOID LEUKEMIA (AML)

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**Objectives:** CPX-351 (Vyxeos<sup>®</sup>; daunorubicin [D] and cytarabine [C] liposome for injection for intravenous use) is approved by the US FDA for the treatment of adults with newly diagnosed therapy-related AML or AML with myelodysplasia-related changes. Primary analysis of the pivotal phase 3 study (NCT01696084) that formed the basis for approval evaluated patients (pts) 60–75 y with newly diagnosed high-risk/secondary AML; after 20.7 mo median follow-up, induction then consolidation with CPX-351 significantly improved median overall survival (OS) vs conventional 7+3, with a comparable safety profile. We now report the prospectively planned, final 5-y follow-up results, including outcomes by age. **Materials and Methods:** Pts were randomized 1:1 to receive 1–2 induction cycles of CPX-351 (100 units/m<sup>2</sup> [C 100 mg/m<sup>2</sup> + D 44 mg/m<sup>2</sup>] as a 90-minute infusion on Days 1, 3, & 5 [2nd induction: Days 1 & 3]) or 7+3 (C 100 mg/m<sup>2</sup>/d continuously for 7 d + D 60 mg/m<sup>2</sup> on Days 1–3 [2nd induction: 5+2]). Pts achieving complete remission (CR) or CR with incomplete platelet/neutrophil recovery (CRi) could receive up to 2 consolidation cycles. Pts received hematopoietic cell transplantation (HCT) at the physician's discretion. Pts were followed until death or up to 5 y after randomization. **Results:** 309 pts were randomized to CPX-351 (n = 153) or 7+3 (n = 156). The Kaplan-Meier (KM)-estimated survival rates were higher for CPX-351 vs 7+3 at 3 y (21% vs 9%) and 5 y (18% vs 8%). Among pts who died, the most common primary cause of death was progressive leukemia (CPX-351: 56%; 7+3: 53%). After a reverse KM-estimated median follow-up of 60.65 mo, improved median OS with CPX-351 vs 7+3 was maintained (9.33 vs 5.95 mo; HR = 0.70 [95% CI: 0.55, 0.91]), with

an HR that was very stable and consistent with the primary analysis. Improved median OS with CPX-351 vs 7+3 was also maintained in pts 60–69 y (9.59 vs 6.87 mo; HR = 0.73 [95% CI: 0.54, 0.99]) and 70–75 y (8.87 vs 5.62 mo; HR = 0.52 [95% CI: 0.34, 0.77]). Among pts who underwent HCT (CPX-351: 35%; 7+3: 25%), the KM-estimated survival rate landmarked from the HCT date was higher for CPX-351 vs 7+3 at 3 y (56% vs 23%), and median OS landmarked from the HCT date was not reached for CPX-351 vs 10.25 mo for 7+3 (HR = 0.51 [95% CI: 0.28, 0.90]). Among pts who achieved CR+CRi (CPX-351: 48%; 7+3: 33%), the KM-estimated survival rate was higher for CPX-351 vs 7+3 at 3 y (36% vs 23%) and at 5 y (30% vs 19%), and median OS was longer with CPX-351 vs 7+3 (21.72 vs 10.41 mo; HR = 0.59 [95% CI: 0.39, 0.88]). Further, 41/73 (56%) pts in the CPX-351 arm and 24/52 (46%) in the 7+3 arm who achieved CR+CRi proceeded to HCT; in these pts, median OS landmarked from the HCT date was not reached for CPX-351 vs 11.65 mo for 7+3 (HR = 0.50 [95% CI: 0.26, 0.97]). **Discussion:** After 5 y of follow-up, improved OS with CPX-351 vs conventional 7+3 chemotherapy was maintained in this phase 3 study, overall and regardless of pt age, in pts who underwent HCT, and among pts who achieved CR+CRi. The longer OS for CPX-351 vs 7+3 in pts who had HCT and those who achieved CR+CRi suggests potentially deeper responses may be achieved with CPX-351. **Conclusion:** These data support prior evidence that CPX-351 can produce or contribute to long-term remission and survival in older pts with newly diagnosed high-risk/secondary AML.

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### HEMATOLOGIA MULTIPROFISSIONAL: UM ESTUDO DE CASO DE LLA

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**Objetivo:** Como em outras doenças hematológicas, a LLA tem suas peculiaridades de assistência, tratamento e transtornos sociais. Este estudo tem como objetivo descrever um caso de LLA do tipo B durante internação no Hemorio envolvendo a atuação das três áreas da residência: biomedicina, enfermagem e serviço social. **Método:** Qualitativo do tipo estudo de caso. As residentes acompanharam o paciente de codinome Tiê. Foram utilizados dados de prontuário, exames laboratoriais, exame físico e ficha social; além de observação em atividades práticas da residência. **Resultados:** Durante o período estudado foi possível fazer o seguinte relato: Tiê, sexo masculino, 60 anos, cor branca, hipertenso, 80 kg, 153 cm, brasileiro, natural do estado da Paraíba, reside no município de Itaboraí/RJ, religião católica, divorciado, quatro filhos, relatou ter ensino fundamental incompleto e trabalhar como auxiliar de serviços gerais. Proveniente do Hospital Municipal Dr. Celso Martins localizado em Cachoeiras de Macacu. Deu entrada no Serviço de Pronto Atendimento (SPA) do Hemorio no dia 07/03/2019 com indicação clínica de leucose aguda. Encaminhado à internação no 5° andar. Tiê teve seu

